ANNEX I

LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES
<table>
<thead>
<tr>
<th>Member State</th>
<th>Marketing Authorisation Holder</th>
<th>Invented Name</th>
<th>Strength</th>
<th>Pharmaceutical form</th>
<th>Route of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>Lilly Deutschland GmbH</td>
<td>STRATTERA 5 mg</td>
<td>5 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td></td>
<td>Saalburgstr. 153 D-61350 Bad Homburg</td>
<td>Hartkapseln</td>
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<td></td>
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<tr>
<td>Germany</td>
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<td></td>
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<td>Netherlands</td>
<td>Eli Lilly Nederland BV</td>
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<td>Oral use</td>
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<td></td>
<td>Postbus 379 3990 GD Houten, Netherland</td>
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<td>Oral use</td>
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<td>Norway</td>
<td>Eli Lilly Norge AS, Grenseveien 99, P.O.Box 6090 Etterstad, NO-0601 Oslo, Norway</td>
<td>Strattera</td>
<td>5 mg</td>
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<td>Oral use</td>
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<tr>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>60 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>5mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Strattera</td>
<td>10mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Strattera</td>
<td>60mg</td>
<td>Capsule,hard</td>
<td>Oral use</td>
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**CITALOPRAM containing medicinal products with Marketing Authorisation in the European Union**

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<tr>
<th>Member State</th>
<th>Marketing Authorisation Holder</th>
<th>Invented Name</th>
<th>Strength</th>
<th>Pharmaceutical form</th>
<th>Route of administration</th>
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</thead>
<tbody>
<tr>
<td><strong>Austria</strong></td>
<td>1A Pharma GmbH, Degengasse 70, 1160 Wien, Austria</td>
<td>Citalopram “1A Pharma” 20mg-Filmtabletten</td>
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<td>Oral use</td>
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<td><strong>Austria</strong></td>
<td>Arcana Arzneimittel GmbH, Zimbagasse 5, 1147 Wien, Austria</td>
<td>Citalopram “Arcana” 10mg-Filmtabletten</td>
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<td>Member State</td>
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<td>Citarcana 20mg-Filmtabellen</td>
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<td>Oral use</td>
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<td>Eostar 20mg-Filmtabellen</td>
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<td>Member State</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Torrex Pharma Ges.m.b.H., Lange Gasse 76/17, 1080 Wien, Austria</td>
<td>Citor 20mg-Filmtabletten</td>
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<td>AKTUAPHARMA N.V. Ambachtenlaan 13 3001 Heverlee</td>
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<td>Citalopram arrow</td>
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<td>Oral use</td>
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<td>Belgium</td>
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<td>Cipramil</td>
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<td>Concentrate for solution for injection</td>
<td>Intravenous use</td>
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<td>Belgium</td>
<td>LUNDBECK N.V. Molièrelaan 225 1050 Brussel</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Oral use</td>
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<td>LUNDBECK N.V. Molièrelaan 225 1050 Brussel</td>
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<td>Oral use</td>
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<td>Belgium</td>
<td>LUNDBECK N.V. Molièrelaan 225 1050 Brussel</td>
<td>Citalopram lundbeck</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Belgium</td>
<td>MERCK N.V. Brusselsesteenweg 288 3090 Overijse</td>
<td>Merck citalopram</td>
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<td>20 mg</td>
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<td>Belgium</td>
<td>SANDOZ N.V. Medialaan 40 1800 Vilvoorde</td>
<td>Citalopram Sandoz</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>THEVA PHARMA BELGIUM N.V. Laarstraat 16 2610 WILRIJK</td>
<td>Citalopram teva</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Belgium</td>
<td>TIEFENBACHER Gmbh Van Der Smissenstrasse 1 D-22767 Hamburg</td>
<td>Citalopram Omega Farma</td>
<td>10 mg</td>
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<td>Oral use</td>
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<td>TIEFENBACHER Gmbh Van Der Smissenstrasse 1 D-22767 Hamburg</td>
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<td>Cyprus</td>
<td>C G PAPALOISOU LTD, 25 ACROPOLEOS STR, 1ST FLOOR, P.O.BOX 21148, ACROPOLIS 1502 LEFKOSIA, CYPRUS</td>
<td>SEROPRAM</td>
<td>20 mg</td>
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<td>Member State</td>
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<td>Invented Name</td>
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<td>Seropram</td>
<td>40mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Intravenous use</td>
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<td>Seropram 20mg</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
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<td>Seropram 10mg</td>
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<td>Cipram 20 mg</td>
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<td>Sepram 20 mg</td>
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<td>Film-coated tablet</td>
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<td>Member State</td>
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<td>Invented Name</td>
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<td>Pram 10 mg</td>
<td>10 mg</td>
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<td>Pram 20 mg</td>
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<td>Cita 10 mg film – coated tablets</td>
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<td>Czech Republic</td>
<td>RANBAXY (UK) LTD., EALING, LONDON Park Lane 95, W1Y 3TA Mayfair, London, UK</td>
<td>Zyloram 10 mg tablety</td>
<td>10 mg</td>
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<td>Oral use</td>
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<td>Cerotor 10</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
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<td>Citalopram &quot;1A Farma&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
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<td>20 mg</td>
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<td>Strength</td>
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<td>60 mg</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK- 2970 Hørsholm, Denmark</td>
<td>Citalopram &quot;Pilva&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK- 2970 Hørsholm, Denmark</td>
<td>Citalopram &quot;Pilva&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK- 2970 Hørsholm, Denmark</td>
<td>Citaham</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
</tr>
<tr>
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<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK-2970 Hørsholm, Denmark</td>
<td>Citaham</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK-2970 Hørsholm, Denmark</td>
<td>Citaham</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Alpharma AS, Harbitzalleen 3, N-0212 Skoyen, Oslo, Norway</td>
<td>Citalopram &quot;Alpharma&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Alpharma AS, Harbitzalleen 3, N-0212 Skoyen, Oslo, Norway</td>
<td>Citalopram &quot;Alpharma&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Alpharma AS, Harbitzalleen 3, N-0212 Skoyen, Oslo, Norway</td>
<td>Citalopram &quot;Alpharma&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Arrow Generics Limited, Unit 2, Eastman Way, UK-SG1 4SZ, Hertz, GB</td>
<td>Citalopram &quot;Arrow&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Arrow Generics Limited, Unit 2, Eastman Way, UK-SG1 4SZ, Hertz, GB</td>
<td>Citalopram &quot;Arrow&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Denmark</td>
<td>Arrow Generics Limited, Unit 2, Eastman Way, UK-SG1 4SZ, Hertz, GB</td>
<td>Citalopram &quot;Arrow&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Billev Pharma Aps, Elmegårdsvej 1A, DK-3630 Jægerspris, Denmark</td>
<td>Rejkapram</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Billev Pharma Aps, Elmegårdsvej 1A, DK-3630 Jægerspris, Denmark</td>
<td>Rejkapram</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Billev Pharma Aps, Elmegårdsvej 1A, DK-3630 Jægerspris, Denmark</td>
<td>Rejkapram</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Copyfarm A/S, Energivej 15, DK-5260 Odense s, Denmark</td>
<td>Citalopram &quot;Copyfarm&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Copyfarm A/S, Energivej 15, DK-5260 Odense s, Denmark</td>
<td>Citalopram &quot;Copyfarm&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Copyfarm A/S, Energivej 15, DK-5260 Odense s, Denmark</td>
<td>Citalopram &quot;Copyfarm&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<tr>
<td>Denmark</td>
<td>Desitin Arzneimittel GmbH, Weg beim Jaeger 214, D-22335 Hamburg, Germany</td>
<td>Desital</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Desitin Arzneimittel GmbH, Weg beim Jaeger 214, D-22335 Hamburg, Germany</td>
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<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Desital</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Durascan Medical Products A/S, C. F. Tietgens Boulevard 40, DK-5220 Odense SØ, Denmark</td>
<td>Citadur</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
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<td>Durascan Medical Products A/S, C. F. Tietgens Boulevard 40, DK-5220 Odense SØ, Denmark</td>
<td>Citadur</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
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<td>Citadur</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>H. Lundbeck A/S, Ottliavej 7-9, DK-2500 Valby, Denmark</td>
<td>Cipramil</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Denmark</td>
<td>H. Lundbeck A/S, Ottliavej 7-9, DK-2500 Valby, Denmark</td>
<td>Cipramil</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>H. Lundbeck A/S, Ottliavej 7-9, DK-2500 Valby, Denmark</td>
<td>Cipramil</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>H. Lundbeck A/S, Ottliavej 7-9, DK-2500 Valby, Denmark</td>
<td>Cipramil</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>H. Lundbeck A/S, Ottliavej 7-9, DK-2500 Valby, Denmark</td>
<td>Cipramil</td>
<td>40 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>H. Lundbeck A/S, Ottliavej 7-9, DK-2500 Valby, Denmark</td>
<td>Cipramil</td>
<td>40 mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citalogebra</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citalogebra</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citalogea</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Citalogea</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Citalogea</td>
<td>60 mg</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citalopram &quot;HEXAL&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citalopram &quot;HEXAL&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citalopram &quot;HEXAL&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citalopram &quot;HEXAL&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citalopram &quot;HEXAL&quot;</td>
<td>60 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citamocal</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Citamocal</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citamocal</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Citamocal</td>
<td>60 mg</td>
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<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Emaxo</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Emaxo</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Emaxo</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Emaxo</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Emaxo</td>
<td>60 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Citalopram &quot;Gea&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Citalopram &quot;Gea&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Citalopram &quot;Gea&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Ivax Scandinavia AB, Birger Jarlsgatan 37, S-11145 Stockholm, Sweden</td>
<td>Citalopram &quot;IVAX&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Ivax Scandinavia AB, Birger Jarlsgatan 37, S-11145 Stockholm, Sweden</td>
<td>Citalopram &quot;IVAX&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Ivax Scandinavia AB, Birger Jarlsgatan 37, S-11145 Stockholm, Sweden</td>
<td>Citalopram &quot;IVAX&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Jacobsen Pharma A/S, Vemmingbund Strandvej 111, DK-6310 Broager, Denmark</td>
<td>Andepril</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Jacobsen Pharma A/S, Vemmingbund Strandvej 111, DK-6310 Broager, Denmark</td>
<td>Andepril</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Jacobsen Pharma A/S, Vemmingbund Strandvej 111, DK-6310 Broager, Denmark</td>
<td>Andepril</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Jacobsen Pharma A/S, Vemmingbund Strandvej 111, DK-6310 Broager, Denmark</td>
<td>Citacip</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Jacobsen Pharma A/S, Vemmingbund Strandvej 111, DK-6310 Broager, Denmark</td>
<td>Citacip</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>Jacobsen Pharma A/S, Vemmingbund Strandvej 111, DK-6310 Broager, Denmark</td>
<td>Citacip</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Jacobsen Pharma A/S, Vemmingbund Strandvej 111, DK-6310 Broager, Denmark</td>
<td>Citalonte</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Jacobsen Pharma A/S, Vemmingbund Strandvej 111, DK-6310 Broager, Denmark</td>
<td>Citalonte</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>NM Pharma A/S, Lautrupvang 8, DK-2750 Ballerup, Denmark</td>
<td>Citalopram &quot;NM&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>NM Pharma A/S, Lautrupvang 8, DK-2750 Ballerup, Denmark</td>
<td>Citalopram &quot;NM&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>NM Pharma A/S, Lautrupvang 8, DK-2750 Ballerup, Denmark</td>
<td>Citalopram &quot;NM&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>40 mg</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde, Denmark</td>
<td>Akarin</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde, Denmark</td>
<td>Akarin</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde, Denmark</td>
<td>Akarin</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde, Denmark</td>
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<td>40 mg</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>PharmaCoDane ApS, Marielundvej 46A, DK-2730 Herlev, Denmark</td>
<td>Citalopram &quot;PCD&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>PharmaCoDane ApS, Marielundvej 46A, DK-2730 Herlev, Denmark</td>
<td>Citalopram &quot;PCD&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>PharmaCoDane ApS, Marielundvej 46A, DK-2730 Herlev, Denmark</td>
<td>Citalopram &quot;PCD&quot;</td>
<td>40 mg</td>
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<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Citalopram &quot;Ratiopharm&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Citalopram &quot;Ratiopharm&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany</td>
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<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Loxopram</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Loxopram</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Loxopram</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Denmark</td>
<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>Citalopram &quot;Biochemie&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>Citalopram &quot;Biochemie&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>Citalopram &quot;Biochemie&quot;</td>
<td>40 mg</td>
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<td>Oral use</td>
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<td>Estonia</td>
<td>ALPHARMA Whiddon ValleyBarnstaple, North Devon EX 32 8NS, England</td>
<td>CITALOPRAM ALPHARMA TABLETS 20 mg</td>
<td>20mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Estonia</td>
<td>HEXAL AG, INDUSTRIESTR.25, 83607 HOLZKIRCHEN, Germany</td>
<td>CIRAL 20</td>
<td>20mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Estonia</td>
<td>HEXAL AG, INDUSTRIESTR.25, 83607 HOLZKIRCHEN, Germany</td>
<td>CIRAL 30</td>
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<td>Oral use</td>
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<td>Estonia</td>
<td>HEXAL AG, INDUSTRIESTR.25, 83607 HOLZKIRCHEN, Germany</td>
<td>CIRAL 40</td>
<td>40mg</td>
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<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
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<td>CIRAL 60</td>
<td>60mg</td>
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<td>Estonia</td>
<td>LANNACHER HEILMITTEL GmbH, Schlossplatz 1, A-8502 Lannach, Austria</td>
<td>PRAM 40MG</td>
<td>40mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Estonia</td>
<td>LANNACHER HEILMITTEL, Schlossplatz 1, A-8502 Lannach, Austria</td>
<td>PRAM 10MG</td>
<td>10mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Estonia</td>
<td>LANNACHER HEILMITTEL, Schlossplatz 1, A-8502 Lannach, Austria</td>
<td>PRAM 20MG</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Estonia</td>
<td>LECIVA A.S., Dolni Mecholupy 130, 102 37 Praha 10, Czech Republic</td>
<td>CITALEC 10</td>
<td>10mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Estonia</td>
<td>LECIVA A.S., Dolni Mecholupy 130, 102 37 Praha 10, Czech Republic</td>
<td>CITALEC 20</td>
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<td>Oral use</td>
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<td>LECIVA A.S., Dolni Mecholupy 130, 102 37 Praha 10, Czech Republic</td>
<td>CITALEC 40</td>
<td>40mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Estonia</td>
<td>LUNDBECK H A/S, Ottiliavej 9, 2500 Copenhagen-Valby, Denmark</td>
<td>CIPRAMIL 10 MG</td>
<td>10mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Estonia</td>
<td>LUNDBECK H A/S, Ottiliavej 9, 2500 Copenhagen-Valby, Denmark</td>
<td>CIPRAMIL 20 MG</td>
<td>20mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Finland</td>
<td>Alpharma A/S, Harbitzalleen 3, Skoyen, 158 SKOYEN, 0212 OSLO, Norway</td>
<td>Citalopram Alpharma</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Alpharma A/S, Harbitzalleen 3, Skoyen, 158 SKOYEN, 0212 OSLO, Norway</td>
<td>Citalopram Alpharma</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Alpharma A/S, Harbitzalleen 3, Skoyen, 158 SKOYEN, 0212 OSLO, Norway</td>
<td>Citalopram Alpharma</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Finland</td>
<td>Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, HERTS SG14SZ, United Kingdom</td>
<td>Citalopram Arrow</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Finland</td>
<td>Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, HERTS SG14SZ, United Kingdom</td>
<td>Citalopram Arrow</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
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<td>Route of administration</td>
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<td>Finland</td>
<td>Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, HERTS SG14SZ, United Kingdom</td>
<td>Citalopram Arrow</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Finland</td>
<td>Desitin Arzneimittel GmbH, Weg beim Jäger 214, 22335 HAMBURG, Germany</td>
<td>Desital</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Desitin Arzneimittel GmbH, Weg beim Jäger 214, 22335 HAMBURG, Germany</td>
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<td>20 mg</td>
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<td>Oral use</td>
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<td>Desitin Arzneimittel GmbH, Weg beim Jäger 214, 22335 HAMBURG, Germany</td>
<td>Desital</td>
<td>40 mg</td>
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<td>Oral use</td>
</tr>
<tr>
<td>Finland</td>
<td>H.Lundbeck A/S, Ottoliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Apertia</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Finland</td>
<td>H.Lundbeck A/S, Ottoliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Apertia</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Finland</td>
<td>H.Lundbeck A/S, Ottoliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Apertia</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
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<td>Finland</td>
<td>H.Lundbeck A/S, Ottiliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Cipramil</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>H.Lundbeck A/S, Ottiliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Cipramil</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>H.Lundbeck A/S, Ottiliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Cipramil</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Finland</td>
<td>H.Lundbeck A/S, Ottiliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Cipramil</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Finland</td>
<td>H.Lundbeck A/S, Ottiliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Cipramil</td>
<td>40 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Finland</td>
<td>H.Lundbeck A/S, Ottiliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Sepram</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Sepram</td>
<td>20 mg</td>
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<td>Sepram</td>
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<td>Oral use</td>
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<td>Finland</td>
<td>H.Lundbeck A/S, Ottiliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Sepram</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Finland</td>
<td>H.Lundbeck A/S, Ottiliavej 9, Valby, 2500 COPENHAGEN, Denmark</td>
<td>Sepram</td>
<td>40 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Hexal A/S, Kanalholmen 8-12, 2650 HVIDOVRE, Denmark</td>
<td>Citamocal</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
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<td>Citamocal</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Hexal A/S, Kanalholmen 8-12, 2650 HVIDOVRE, Denmark</td>
<td>Citamocal</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hexal A/S, Kanalholmen 8-12, 2650 HVIDOVRE, Denmark</td>
<td>Citamocal</td>
<td>60 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Emocal</td>
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<td>Oral use</td>
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<td>Hexal A/S, Kanalholmen 8-12, 2650 HVIDOVRE, Denmark</td>
<td>Emocal</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hexal A/S, Kanalholmen 8-12, 2650 HVIDOVRE, Denmark</td>
<td>Emocal</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Finland</td>
<td>Hexal AG, Industriestrasse 25, 83607 HOLZKIRCHEN, Germany</td>
<td>Citalopram Hexal</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Hexal AG, Industriestrasse 25, 83607 HOLZKIRCHEN, Germany</td>
<td>Citalopram Hexal</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Citalopram Hexal</td>
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<td>Oral use</td>
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<td>Hexal AG, Industriestrasse 25, 83607 HOLZKIRCHEN, Germany</td>
<td>Citalopram Hexal</td>
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<td>Merck NM AB, Ynglingagatan 14, 11347, P.Box 22033, S-10435 Stockholm, Sweden</td>
<td>Citalopram Generics</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Merck NM AB, Ynglingagatan 14, 11347, P.Box 22033, S-10435 Stockholm, Sweden</td>
<td>Citalopram Generics</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Finland</td>
<td>Merck NM AB, Ynglingagatan 14, 11347, P.Box 22033, S-10435 Stockholm, Sweden</td>
<td>Citalopram Generics</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Merck NM AB, Ynglingagatan 14, 11347, P.Box 22033, S-10435 Stockholm, Sweden</td>
<td>Citalopram Generics</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, 89070 ULM, Germany</td>
<td>Citalopram-Ratiopharm</td>
<td>10 mg</td>
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<td>CitaLich 40 mg Filmtabletten</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Greece</td>
<td>ALVIA AE, 18Km Leoforos Marathonos, 15344 Pallini Attikis, Greece</td>
<td>CITALOPRAM/ALVIA</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Greece</td>
<td>ALVIA AE, 18Km Leoforos Marathonos, 15344 Pallini Attikis, Greece</td>
<td>CITALOPRAM/ALVIA</td>
<td>40mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Greece</td>
<td>CHRISPA ALFA, PHARMACUTICALS, 16Km Marathonos Av., 15344 Pallini Attikis, GREECE</td>
<td>PRICITAL</td>
<td>40mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Greece</td>
<td>ELPEN AE, 21Km Leoforos Marathonos, 19009 Pikermi Attikis, Greece</td>
<td>CINAPEN</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Greece</td>
<td>GENEPHARM AEBE, 18 Km Marathonos Av., 15351 Palini Attikis, Greece</td>
<td>CITALOPRAM/GENEPHARM</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Greece</td>
<td>GENEPHARM AEBE, 18 Km Marathonos Av., 15351 Palini Attikis, Greece</td>
<td>CITALOPRAM/GENEPHARM</td>
<td>40mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<tr>
<td>Greece</td>
<td>LUNDBECK HELLAS, 64a Kifissias Aven, 15125 Maroussi, Greece</td>
<td>SEROPRAM</td>
<td>10mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Greece</td>
<td>LUNDBECK HELLAS, 64a Kifissias Aven, 15125 Maroussi, Greece</td>
<td>SEROPRAM</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>LUNDBECK HELLAS, 64a Kifissias Aven, 15125 Maroussi, Greece</td>
<td>SEROPRAM</td>
<td>40mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Greece</td>
<td>LUNDBECK HELLAS, 64a Kifissias Aven, 15125 Maroussi, Greece</td>
<td>SEROPRAM</td>
<td>40mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Intravenous use</td>
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<td>Greece</td>
<td>LUNDBECK HELLAS, 64a Kifissias Aven, 15125 Maroussi, Greece</td>
<td>SEROPRAM</td>
<td>40mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Greece</td>
<td>NOVEXAL HELLAS, Agiou Dimitriou 25, 17455 Kalamaki, Greece</td>
<td>CITALOPRAM/NOVEXAL</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Greece</td>
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<td>CITALOPRAM/NOVEXAL</td>
<td>10mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Greece</td>
<td>SANDOZ AUSTRIA, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>CITALON</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>SANDOZ AUSTRIA, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>CITALON</td>
<td>40mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>VERISFIELD LTD UK, 41 Chalton Street, London, NW1 1JD, U.K.</td>
<td>SEROCEL</td>
<td>40mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Actavis Nordic A/S, 2970 Horsholm, Hammervej 7. Denmark</td>
<td>OROPRAM 10 mg filmtabletta</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>Actavis Nordic A/S, 2970 Horsholm, Hammervej 7. Denmark</td>
<td>OROPRAM 20 mg filmtabletta</td>
<td>20 mg</td>
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<td>Oral use</td>
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<td>Hungary</td>
<td>Actavis Nordic A/S, 2970 Horsholm, Hammervej 7. Denmark</td>
<td>OROPRAM 40 mg filmtabletta</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Hungary</td>
<td>Hexal Hungária Kft., Timár u. 20, 1034 Budapest, Hungary</td>
<td>CITAPRAM 20 mg filmtabletta</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Hungary</td>
<td>Hexal Hungária Kft., Timár u. 20, 1034 Budapest, Hungary</td>
<td>CITAPRAM 30 mg filmtabletta</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Hexal Hungária Kft., Timár u. 20, 1034 Budapest, Hungary</td>
<td>CITAPRAM 40 mg filmtabletta</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>Hungary</td>
<td>Hexal Hungária Kft., Timár u. 20, 1034 Budapest, Hungary</td>
<td>CITAPRAM 60 mg filmtabletta</td>
<td>60 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Lundbeck Hungária Kft, Montevideó utca 3/B, 1037, Budapest, Hungary</td>
<td>APERTIA 20 mg filmtabletta</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Lundbeck Hungária Kft, Montevideó utca 3/B, 1037, Budapest, Hungary</td>
<td>CIPRAM 20 mg filmtabletta</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
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<td>SEPRAM 20 mg filmtabletta</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Lundbeck Hungária Kft, Montevideó utca 3/B, 1037, Budapest, Hungary</td>
<td>SEROPRAM 20 mg filmtabletta</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Lundbeck Hungária Kft, Montevideó utca 3/B, 1037, Budapest, Hungary</td>
<td>SEROPRAM 20 mg/0,5 ml koncentrátum infúzióhoz</td>
<td>20 mg/0,5 ml</td>
<td>Concentrate for solution for infusion</td>
<td>Intravenous infusion</td>
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<td>Hungary</td>
<td>Lundbeck Hungária Kft, Montevideó utca 3/B, 1037, Budapest, Hungary</td>
<td>SEROPRAM 40 mg/ml cseppek</td>
<td>40 mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Hungary</td>
<td>Merck Generics Limited UK EN61AG Herts, Potters Bar, Darkes Lane, Albany Gate, U.K.</td>
<td>CITAGEN 10 mg filmtabletta</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Merck Generics Limited UK EN61AG Herts, Potters Bar, Darkes Lane, Albany Gate, U.K.</td>
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<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Ranbaxy UK Ltd.Uxbridge Road 97 London, W5 5TL, U.K.</td>
<td>ZYLORAM 10 mg filmtabletta</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Ranbaxy UK Ltd.Uxbridge Road 97 London, W5 5TL, U.K.</td>
<td>ZYLORAM 20 mg filmtabletta</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Ranbaxy UK Ltd.Uxbridge Road 97 London, W5 5TL, U.K.</td>
<td>ZYLORAM 40 mg filmtabletta</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Ratiopharm Hungary Kft., Uzsoki út 36/A, 1145 Budapest, Hungary</td>
<td>CITALOPRAM-RATIOPHARM 20 mg filmtabletta</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Hungary</td>
<td>Sandoz GmbH, Biochemiestrasse 10°, 6250 Kundl, Austria</td>
<td>CITALON 10 mg filmtabletta</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
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<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Hungary</td>
<td>Sandoz GmbH, Biochemiestrasse 10°, 6250 Kundl, Austria</td>
<td>CITALON 20 mg filmtabletta</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>Sandoz GmbH, Biochemiestrasse 10°, 6250 Kundl, Austria</td>
<td>CITALON 40 mg filmtabletta</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Torrex Pharma GmbH, Lange gasse 76/12, A-1080 Wien, Austria</td>
<td>SEROTOR 10 mg filmtabletta</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Torrex Pharma GmbH, Lange gasse 76/12, A-1080 Wien, Austria</td>
<td>SEROTOR 20 mg filmtabletta</td>
<td>20 mg</td>
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<td>Oral use</td>
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<td>Hungary</td>
<td>Torrex Pharma GmbH, Lange gasse 76/12, A-1080 Wien, Austria</td>
<td>SEROTOR 40 mg filmtabletta</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Iceland</td>
<td>H. Lundbeck A/Sm 9 Ottliavej DK-2500 Valby Copenhagen</td>
<td>Cipramil</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>H. Lundbeck A/Sm 9 Ottliavej DK-2500 Valby Copenhagen</td>
<td>Cipramil</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>H. Lundbeck A/Sm 9 Ottiliavej DK-2500 Valby Copenhagen</td>
<td>Cipramil</td>
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<td>Cipramil</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>H. Lundbeck A/Sm 9 Ottiliavej DK-2500 Valby Copenhagen</td>
<td>Cipramil</td>
<td>40 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Iceland</td>
<td>H. Lundbeck A/Sm 9 Ottiliavej DK-2500 Valby Copenhagen</td>
<td>Cipramil</td>
<td>40 mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Oral use</td>
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<tr>
<td>Iceland</td>
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<td>Oropram</td>
<td>10 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Actavis hf., Reykjavikurvegi 76-78, 220 Hafnarfjörður, Iceland</td>
<td>Oropram</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Iceland</td>
<td>Actavis hf., Reykjavikurvegi 76-78, 220 Hafnarfjörður, Iceland</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Strength</td>
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<td>40 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Clonmel Healthcare Limited, Waterford Road, Clonmel, Co. Tipperary, Ireland</td>
<td>Ciprotan</td>
<td>10 mg</td>
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<td>Oral use</td>
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<td>Clonmel Healthcare Limited, Waterford Road, Clonmel, Co. Tipperary, Ireland</td>
<td>Ciprotan</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>Clonmel Healthcare Limited, Waterford Road, Clonmel, Co. Tipperary, Ireland</td>
<td>Ciprotan</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Ireland</td>
<td>Lundbeck (Ireland) Limited, 14 Deansgrange Industrial Estate, Blackrock, Co. Dublin, Ireland</td>
<td>Cipramil</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Ireland</td>
<td>Lundbeck (Ireland) Limited, 14 Deansgrange Industrial Estate, Blackrock, Co. Dublin, Ireland</td>
<td>Cipramil</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>Lundbeck (Ireland) Limited, 14 Deansgrange Industrial Estate, Blackrock, Co. Dublin, Ireland</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Strength</td>
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<td>Ireland</td>
<td>McDermott Laboratories Ltd t/a Gerard Laboratories, 35 Baldoyle Industrial Estate Grange Road, Dublin 13, Ireland</td>
<td>Ciprager</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>McDermott Laboratories Ltd t/a Gerard Laboratories, 35 Baldoyle Industrial Estate Grange Road, Dublin 13, Ireland</td>
<td>Ciprager</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>McDermott Laboratories Ltd t/a Gerard Laboratories, 35 Baldoyle Industrial Estate Grange Road, Dublin 13, Ireland</td>
<td>Ciprager</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>Pinewood Laboratories Ltd Ballymacarbry, Clonmel, Co. Tipperary, Ireland</td>
<td>Ciprapinie</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Pinewood Laboratories Ltd Ballymacarbry, Clonmel, Co. Tipperary, Ireland</td>
<td>Ciprapinie</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>Pinewood Laboratories Ltd Ballymacarbry, Clonmel, Co. Tipperary, Ireland</td>
<td>Ciprapinie</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>Ranbaxy Ireland Limited, Cork Road, Cashel, Co. Tipperary, Ireland</td>
<td>Citalopram</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
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<td>Ranbaxy Ireland Limited, Cork Road, Cashel, Co. Tipperary, Ireland</td>
<td>Citalopram</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ranbaxy Ireland Limited, Cork Road, Cashel, Co. Tipperary, Ireland</td>
<td>Citalopram</td>
<td>40mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>Rowex Ltd, Bantry, Co Cork, Ireland</td>
<td>Citalopram</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>Alfred E. Tiefenbacher (GmbH &amp; Co. KG) Van-der-Smissen-Str. 1 22767 Hamburg - Germany</td>
<td>Citalopram Omega</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Alfred E. Tiefenbacher (GmbH &amp; Co. KG) Van-der-Smissen-Str. 1 22767 Hamburg - Germany</td>
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<td>Citalopram Allen</td>
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<td>Oral use</td>
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<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Concentrate for solution for infusion</td>
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<td>Oral drops, solution</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Film-coated tablet</td>
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| Italy       | Recordati S.p.A.  
Via Matteo Civitali, 1  
20148 Milano  
Italy          | Elopram       | 40 mg    | Film-coated tablet           | Oral use                |
| Italy       | Recordati S.p.A.  
Via Matteo Civitali, 1  
20148 Milano  
Italy          | Elopram       | 40 mg/ml | Concentrate for solution for infusion | Intravenous use         |
| Italy       | Recordati S.p.A.  
Via Matteo Civitali, 1  
20148 Milano  
Italy          | Elopram       | 40 mg/ml | Oral drops, solution         | Oral use                |
| Italy       | Sandoz S.p.A.  
Largo Umberto Boccioni, 1  
21040 Origgio - Varese  
Italy          | Citalopram Sandoz | 20 mg    | Film-coated tablet           | Oral use                |
| Italy       | Sandoz S.p.A.  
Largo Umberto Boccioni, 1  
21040 Origgio - Varese  
Italy          | Citalopram Sandoz | 40 mg    | Film-coated tablet           | Oral use                |
| Italy       | So. Se. Pharm S.r.l.  
Via Dei Castelli Romani, 22  
00040 Pomezia - Roma  
Italy          | Frimaind      | 20 mg    | Film-coated tablet           | Oral use                |
| Italy       | So. Se. Pharm S.r.l.  
Via Dei Castelli Romani, 22  
00040 Pomezia - Roma  
Italy          | Frimaind      | 40 mg    | Film-coated tablet           | Oral use                |
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<tr>
<th>Member State</th>
<th>Marketing Authorisation Holder</th>
<th>Invented Name</th>
<th>Strength</th>
<th>Pharmaceutical form</th>
<th>Route of administration</th>
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<td>Winthrop Médicaments 9, boulevard Romain-Rolland 75 159 Paris Cedex 14 - France</td>
<td>Citalopram Winthrop</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Citalopram Winthrop</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Latvia</td>
<td>Alpharma Ltd, UK, Whiddon Valley Barnstable Devon, EX32 8NS UNITED KINGDOM</td>
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<td>20 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Latvia</td>
<td>H. Lundbeck A/S, Ottliavej 9 Valby DK-2500, Copenhagen DENMARK</td>
<td>Cipramil</td>
<td>40mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Intravenous use</td>
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<td>Cipramil</td>
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<td>Coated tablet</td>
<td>Oral use</td>
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<td>Latvia</td>
<td>H. Lundbeck A/S, Ottliavej 9 Valby DK-2500, Copenhagen DENMARK</td>
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<td>Oral use</td>
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<td>Latvia</td>
<td>Hexal, Industriestrasse 25 D – 83607 Holzkirchen GERMANY</td>
<td>Ciral</td>
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<td>Hexal, Industriestrasse 25 D – 83607 Holzkirchen GERMANY</td>
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<td>Lannacher Heilmittel GmbH, Schloßplatz 1 A-8502 Lannach AUSTRIA</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Ciral 20</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Coated tablet</td>
<td>Oral use</td>
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<td>Film-coated tablet</td>
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<td>Chemische Tempelhof GMBH, Lengedestr. 42A, D-13407 Berlin, Germany</td>
<td>Citalopram VON CT</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
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<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>SANDOZ S.A., Telecom Gardens, Mediaalan 40, B-1800 Vilvoorde, Belgium</td>
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<td>Member State</td>
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<td>H Lundbeck AS, 9, Ottilavey, DK 2500 Vallay Copenhagen</td>
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<td>Netherlands</td>
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<td>Netherlands</td>
<td>Alfred Tiefenbacher (GmbH &amp; Co. KG) Van-der-Smissen-Strasse 1 22767 Hamburg</td>
<td>Citalopram Omega 40 mg, film coated tablets</td>
<td>40 mg</td>
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<td>Netherlands</td>
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<td>Citalopram Tiefenbacher 10 mg, film coated tablets</td>
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<td>Citalopram 10 A, film coated tablets</td>
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<td>Member State</td>
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<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Pram</td>
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<td>Coated tablet</td>
<td>Oral use</td>
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<td>Pram</td>
<td>40 mg</td>
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<td>Oral use</td>
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<td>Leciva A.S., U kabelovny 130, Dolni Mechołupy, 102 37 Prague 10, Czech Republic</td>
<td>Cimax</td>
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<td>Member State</td>
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<td>Arrow Generics, Ltd., Unit 2 - Eastman Way SG1 4SZ Stevenage – Hertfordshire, U.K.</td>
<td>Citalopram Arrow 10 mg comprimidos</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>60 mg</td>
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<td>Farmoquímica Baldacci, S.A., Rua Duarte Galvão, n.º 44 1549-005 Lisboa Portugal</td>
<td>Citalopram Nozat 10 mg comprimidos revestidos</td>
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<td>Cipramil</td>
<td>40 mg/ml</td>
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<td>Medilusa - Comércio e Indústria de Especialidades Farmacêuticas, Lda., Rua Duarte Galvão, n.º13 R/C Esq. 1500-252 Lisboa Portugal</td>
<td>Citalopram Medilusa 10 mg comprimidos revestidos</td>
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<td>Merck Genéricos - Produtos Farmacêuticos, Lda., Rua Alfredo da Silva, 3 - C - 4º 1300-040 Lisboa Portugal</td>
<td>Citalopram Merck Genéricos 20 mg comprimidos revestidos</td>
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<td>Film-coated tablet</td>
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<td>Slovak Republic</td>
<td>Desitin Arzneimittel GmbH, Weg beim Jäger 214, D - 22 335 Hamburg</td>
<td>DESITAL 10mg</td>
<td>10mg</td>
<td>Film-coated tablet</td>
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<td>Slovak Republic</td>
<td>Desitin Arzneimittel GmbH, Weg beim Jäger 214, D - 22 335 Hamburg</td>
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<td>20mg</td>
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<td>Slovak Republic</td>
<td>Desitin Arzneimittel GmbH, Weg beim Jäger 214, D - 22 335 Hamburg</td>
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<td>Generics[UK] Ltd., Station Close, Potters Bar, , UK - Herts EN6 1TL</td>
<td>RONAL 20mg</td>
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<td>Slovak Republic</td>
<td>GEROT Pharmazeutika GmbH Arnethgasse 3, A - 1160 Wien, Austria</td>
<td>PRAM</td>
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<td>Route of administration</td>
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<td>Concentrate for solution for infusion</td>
<td>Intravenous use</td>
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<td>H.Lundbeck A/S, Ottiliavej 9, DK - 2500 Copenhagen Valby</td>
<td>SEROPRAM 20mg</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>SEROPRAM 40mg</td>
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<td>ZYLORAM</td>
<td>10 mg</td>
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<td>Oral use</td>
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<td>ZYLORAM</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Sandoz GmbH, Biochemiestrasse 10, A - 6250 Kundl</td>
<td>CITALON 10</td>
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<td>Sandoz GmbH, Biochemiestrasse 10, A - 6250 Kundl</td>
<td>CITALON 20</td>
<td>20mg</td>
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<td>Oral use</td>
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<td>CITALEC</td>
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<td>Merck, Proizvodnja in prodaja farmacevskih in kemijskih proizvodov, d.o.o., Dunajska 156, SI-1000 Ljubljana, Slovenia</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Strength</td>
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<td>Route of administration</td>
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<td>Route of administration</td>
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ESCITALOPRAM containing medicinal products with Marketing Authorisation in the European Union

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**FLUOXETINE containing medicinal products with Marketing Authorisation in the European Union**

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<td>Fluoxetin „1A Pharma“ 20mg-Kapseln</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Austria</td>
<td>Arcana Arzneimittel GmbH, Zimbagasse 5, 1147 Wien, Austria</td>
<td>Fluoxetin “Arcana“ 20mg-Kapseln</td>
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<td>Eli Lilly Ges.m.b.H., Kölblgasse 8-10, 1030 Wien, Austria</td>
<td>Fluctine Dura Pac 90mg- Retardkapseln</td>
<td>90mg</td>
<td>Prolonged-release capsule, hard</td>
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<td>20mg</td>
<td>Capsule, hard</td>
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<td>20mg</td>
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<td>Oral use</td>
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<td>Eli Lilly Ges.m.b.H., Kölblgasse 8-10, 1030 Wien, Austria</td>
<td>Fluctine 20mg/5ml-orale Lösung</td>
<td>20mg</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Oral use</td>
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<td>F.Joh.Kwizda Ges.m.b.H., Dr.Karl Lueger Ring 6, 1010 Wien, Austria</td>
<td>Fluoxetin „Kwizda“ 20mg-Kapseln</td>
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<td>Capsule, hard</td>
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<td>Faromed Handelsges.m.b.H., Johann Strauß Gasse 7, 1040 Wien, Austria</td>
<td>NuFluo 20mg-Kapseln</td>
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<td>Genericon Pharma Ges.m.b.H., Schloßplatz 1, 8502 Lannach, Austria</td>
<td>Fluoxenorm “Genericon” 20mg-Filmtabletten</td>
<td>20mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Fluoxenorm “Genericon” 20mg/5ml-orale Lösung</td>
<td>4mg/1ml</td>
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<td>Hexal Pharma GmbH, Wilhelmimenstr. 91, 1160 Wien, Austria</td>
<td>Flux „Hexal“ 20mg-Kapseln</td>
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<td>Hexal Pharma GmbH, Wilhelmimenstr. 91, 1160 Wien, Austria</td>
<td>Flux „Hexal“ Tabs 10mg-Tabletten</td>
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<td>Lannacher Heilmittel GmbH, Schloßplatz 1, 8502 Lannach, Austria</td>
<td>Mutan 20mg-Kapseln</td>
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<td>Oral use</td>
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<td>Mutan 20mg-Filmtabletten</td>
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<td>Film-coated tablet</td>
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<td>Lannacher Heilmittel GmbH, Schloßplatz 1, 8502 Lannach, Austria</td>
<td>Fluoxetin „Lannacher“ 20mg-Kapseln</td>
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<td>Oral use</td>
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<td>Austria</td>
<td>Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, IRL</td>
<td>Floccin 20mg/5ml-Lösung zum Einnehmen</td>
<td>4mg/1ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>Austria</td>
<td>Ratiopharm Arzneimittel Vertriebs Ges.m.b.H., Albert Schweitzer-Gasse 3, 1140 Wien, Austria</td>
<td>Fluoxibene 20mg-Kapseln</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>S.Med Handels GmbH, Bräunerstr. 3, 1010 Wien, Austria</td>
<td>FluxoMed 20mg-Kapseln</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Sanova Pharma Ges.m.b.H., Haidestr. 4, 1110 Wien, Austria</td>
<td>Positivum-Kapseln</td>
<td>20mg</td>
<td>Capsule, hard</td>
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<td>Stada Arzneimittel GmbH, Muthgasse 36, 1190 Wien, Austria</td>
<td>Felicium 20mg-Tabletten</td>
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<td>Oral use</td>
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<td>Fluoxetine „Stada“ 20mg-Kapseln</td>
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<td>Belgium</td>
<td>3 DDD PHARMA Diestersteenweg 349, 3510 Kermt, Belgium</td>
<td>Prosimed</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Belgium</td>
<td>AKTUAPHARMA N.V. Ambachtenlaan 13, 3001 Heverlee, Belgium</td>
<td>Prozac</td>
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<td>APOGENPHARMA B.V. Europark Oost 34, 9100 St. Niklaas, Belgium</td>
<td>Fluoxetine PSI</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>DOCPHARMA N.V., Ambachtenlaan 13 H, B-3001 Heverlee, Belgium</td>
<td>Docfluoxetine</td>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>ELI LILLY BENELUX S.A., Rue de l'Etuve 52, 1000 Bruxelles, Belgium</td>
<td>Fluoxetine Lilly</td>
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<td>Oral use</td>
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<td>ELI LILLY BENELUX S.A., Rue de l'Etuve 52, 1000 Bruxelles, Belgium</td>
<td>Fontex</td>
<td>20 mg</td>
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<td>Oral use</td>
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<td>ELI LILLY BENELUX S.A., Rue de l'Etuve 52, 1000 Bruxelles, Belgium</td>
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<td>Oral use</td>
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<td>Prozac</td>
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<td>ELI LILLY BENELUX S.A., Rue de l'Etuve 52, 1000 Bruxelles, Belgium</td>
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<td>Prozac Dispersible</td>
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<td>Fluoxetine EG</td>
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<td>Laboratoires S.M.B. Rue de la Pastorale 26, 1080 Bruxelles, Belgium</td>
<td>Fluoxone Divule</td>
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<td>Merck Fluoxetine</td>
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<td>OLYMPO PHARMA B.V.B.A. Lange Munteplein 7b 4, 8500 Kortrijk, Belgium</td>
<td>Prozac</td>
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<td>Oral use</td>
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<td>SANDOZ N.V. Medialaan 40 1800 Vilvoorde, Belgium</td>
<td>Fluoxetine Sandoz</td>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Fluox</td>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>TEVA PHARMA BELGIUM N.V. Laarstraat 16, 2610 WILRIJK, Belgium</td>
<td>Fluoxetine Teva</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>TOPGEN N.V. Demunterlaan 1 b 9, 1090 Brussel, Belgium</td>
<td>Fluoxetop</td>
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<td>Cyprus</td>
<td>COSTAKIS TSISIOS &amp; CO LTD, 25 THESSALONIKIS STR, P.O BOX 56495, 3307 LEMESOS, CYPRUS</td>
<td>FOKESTON</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>PHADISCO LTD, 185 GIANOU KRAINIDIOTI AVENUE, LATSIA, P.O.BOX 22173, 1518 LEFKOSIA, CYPRUS</td>
<td>LADOSE</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>PHARMACEUTICAL TRADING CO LTD, 33 ARTEMIDOS AVENUE, P.O. BOX 40628, 6306 LARNACA, CYPRUS</td>
<td>FLUOXETINE</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Cyprus</td>
<td>REMEDICA LTD, AHARNON STR, P.O.BOX 51706, INDUSTRIAL ESTATE 3508 LEMESOS, CYPRUS</td>
<td>PLAZERON</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Cyprus</td>
<td>MEDOCHEMIE LTD, P.O.BOX 51409, 3505 LEMESOS, CYPRUS</td>
<td>MAGRILAN</td>
<td>20 mg</td>
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<td>Czech Republic</td>
<td>APOTEX EUROPE LTD., READING, Rowan House, 41 London Street, RG1 4PS, Reading, Berkshire, UK</td>
<td>APO-FLUOXETINE</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Czech Republic</td>
<td>EGIS PHARMACEUTICALS LTD., BUDAPEŞT, Keresztüri út 30-38, 1106 Budapest, Hungary</td>
<td>FLOXET 10 MG</td>
<td>10 mg</td>
<td>Capsule, hard</td>
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<td>EGIS PHARMACEUTICALS LTD., BUDAPEŠT, Keresztúri út 30-38, 1106 Budapest, Hungary</td>
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<td>Czech Republic</td>
<td>ELI LILLY ČR s.r.o., Praha, Czech Republic</td>
<td>PROZAC</td>
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<td>HEXAL AG, HOLZKIRCHEN, Industriestraße 25, 836 07 Holzkirchen, Germany</td>
<td>FLUOXIN</td>
<td>20 mg</td>
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<td>Czech Republic</td>
<td>KRKA, D.D., NOVO MĚSTO, Šmajoška cesta 6, 8501 Novo Město, Slovenia</td>
<td>FLUVAL</td>
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<td>Oral use</td>
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<td>LABORATOIRES IREX, LE PLESSIS-ROBINSON, Avenue Galilée 22, 923 50 Le Plessis Robinson, France</td>
<td>FLUMIREX</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Czech Republic</td>
<td>LEK PHARMACEUTICALS D.D., LJUBLJANA, Verovškova 57, 1526 Ljubljana, Slovenia</td>
<td>PORTAL</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Czech Republic</td>
<td>MEDOCHEMIE LTD., LIMASSOL, Constantinoupolεος St. 1-10, P.O.Box 51409, 3505 Limassol, Cyprus</td>
<td>MAGRIŁAN</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>RATIOPHARM GMBH, ULM, Graf-Arco-Strasse 3, 890 79 Ulm, Germany</td>
<td>FLUOXETIN-RATIOPHARM 20 MG</td>
<td>20 mg</td>
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<td>Oral use</td>
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<td>Czech Republic</td>
<td>SVUS PHARMA A.S., HRADEC KRÁLOVÉ, Škroupova 957, 500 02 Hradec Králové, Czech Republic</td>
<td>FLUZAK</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Czech Republic</td>
<td>ZENTIVA A.S., HLOHOVEC, Nitrianska 100, 920 27 Hlohovec, Slovak Republic</td>
<td>DEPRENON</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>ZENTIVA A.S., PRAGUE, U Kabelovny 130, 102 37 Praha 10 - Horní Měcholupy, Czech Republic</td>
<td>DEPREX LÉČIVA</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>1A Farma A/S, Herstedøstervej 27-29, DK-2620 Albertslund, Denmark</td>
<td>Fluoxetin &quot;1A Farma&quot;</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK-2970 Hørsholm, Denmark</td>
<td>Afeksin</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK-2970 Hørsholm, Denmark</td>
<td>Afeksin</td>
<td>20 mg</td>
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<td>Alpharma Aps, Harbitzalleen 3, N-0212 Skøyen, Oslo, Norway</td>
<td>Fluoxetin &quot;Alpharma&quot;</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>BMM Pharma AB, Blasieholmgatan 2, S-11148 Stockholm, Sweden</td>
<td>Fluoxetin &quot;BMM Pharma&quot;</td>
<td>20 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Copyfarm A/S, Energivej 15, DK-5260 Odense S, Denmark</td>
<td>Fluoxetin &quot;Copyfarm&quot;</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Denmark</td>
<td>Durascan Medical Products A/S, C. F. Tietgens Boulevard 40, DK-5220 Odense SØ, Denmark</td>
<td>Fondur</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Eli Lilly Danmark A/S, Nybrogade 110, DK-2800 Kongens Lyngby, Denmark</td>
<td>Fontex</td>
<td>20 mg</td>
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<td>Eli Lilly Danmark A/S, Nybrogade 110, DK-2800 Kongens Lyngby, Denmark</td>
<td>Fontex</td>
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<td>Eli Lilly Danmark A/S, Nybrogade 110, DK-2800 Kongens Lyngby, Denmark</td>
<td>Fontex</td>
<td>20 mg</td>
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<td>Fonzac</td>
<td>20 mg</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Generics (UK) Ltd., Station Close, Potters Bar, UK-EN61TL Hertfordshire, GB</td>
<td>Fluoxetine &quot;NM&quot;</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Fluxantin</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Medis Danmark A/S, H. C. Andersens Boulevard 2, DK-1780 København V, Denmark</td>
<td>Fluoxetine &quot;Medis&quot;</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Medis Danmark A/S, H. C. Andersens Boulevard 2, DK-1780 København V, Denmark</td>
<td>Fluoxetine &quot;Medis&quot;</td>
<td>4 mg/ml</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Orion Corporation, Orionintie 1, SF-02200 Espoo, Finland</td>
<td>Flutin</td>
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<td>Denmark</td>
<td>PharmaCoDane ApS, Marielundvej 46A, DK-2730 Herlev, Denmark</td>
<td>Folizol</td>
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<td>Denmark</td>
<td>PSI NV, Kraanlei 27, B-9000 Gent, Belgium</td>
<td>Fluoxetin &quot;PSI&quot;</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Denmark</td>
<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Austria</td>
<td>Fluoxetin &quot;Sandoz&quot;</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Teva Pharma B.V., Industrieweg 23, NL-3640 AE, Mijdrecht, Netherland</td>
<td>Fluoxetin &quot;Teva&quot;</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>CHEMICAL WORKS OF GEDEON RICHTER LTD., GYÖMRÖI UT 19-21, H-1103 BUDAPEST, Hungary</td>
<td>FRAMEX</td>
<td>20mg</td>
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<td>Oral use</td>
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<td>Eli Lilly Holding Ltd, Kingsclere Road, Basingstocke, Hampshire, RG216XA, UK</td>
<td>PROZAC</td>
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<td>Oral use</td>
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<td>HEXAL AG, INDUSTRIESTR.25, 83607 HOLZKIRCHEN, Germany</td>
<td>FLUX</td>
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<td>Oral use</td>
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<td>Estonia</td>
<td>MEDOCHEMIE LTD.CONSTANTINOPOL STREET 1-10P.O.BOX 1409, LIMASSOL Cyprus</td>
<td>FLUOXETIN MEDOCHEMIE</td>
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<td>Oral use</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>NYCOMED SEFA, Jaama 55B, Põlva, Estonia</td>
<td>NYCOFLOX</td>
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<td>Oral use</td>
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<td>Zentiva a.s., U kabelovny 130, 102 37 Prague 10, Czech Republic</td>
<td>DEPRENON</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Alpharma A/S, Harbitzalleen 3, Skoyen, 158 SKOYEN, 0212 OSLO, Norway</td>
<td>Fluoxal</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Ennapharma Oy, Vanhankyläntie 44 B, Post Box 152, 04401 Järvenpää, Finland</td>
<td>Fluoksetiini Ennapharma</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Generics (UK) Limited, Station Close, Potters Bar, HERTFORDSHIRE EN61TL, United Kingdom</td>
<td>Fluoxetin Generics</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Hexal A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Fluxantin</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Laboratoires SMB S.A., Rue de la Pastorale 26-28, 1080 BRUSSELS, Belgium</td>
<td>Fluoxone</td>
<td>20 mg</td>
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<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
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<td>Merckle GmbH, Ludwig-Merckle-Strasse 3, P.O. BOX 1161, 89143 BLAUBEUREN, Germany</td>
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<td>Seronil</td>
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<td>Film-coated tablet</td>
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<td>Ranbaxy UK Limited, 95 Park Lane, Mayfair, LONDON W1K 3TE, United Kingdom</td>
<td>Fluoxetine Ranbaxy</td>
<td>20 mg</td>
<td>Capsule</td>
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<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, 89070 ULM, Germany</td>
<td>Fluoxetin-Ratiopharm</td>
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<td>Ratiopharm Oy, P.B. 67, 02631 Espoo, Finland</td>
<td>Fluoxetin-Ratiopharm</td>
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<td>Capsule</td>
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<td>Neuraxpharm Arzneimittel GmbH &amp; Co.KG Postfach 400455 D-40244 Langenfeld</td>
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<td>Capsule, hard</td>
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<td>Rodleben Pharma GmbH Postfach 205 D-06855 Rodleben</td>
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<td>Germany</td>
<td>S.A. Laboratoires S.M.B. Rue-de-la-Pastorale 26-28 B-1080 Bruxelles</td>
<td>Fluxone Divule 20 mg ueberzogene Tabletten</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Germany</td>
<td>Sandoz Pharmaceuticals GmbH Dieselstr. 5 D-70839 Gerlingen</td>
<td>Fluoxetin Sandoz 20 mg Tabletten</td>
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<td>Sandoz Pharmaceuticals GmbH Dieselstr. 5 D-70839 Gerlingen</td>
<td>Fluoxetin Sandoz 20 mg Hartkapseln</td>
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<td>Oral use</td>
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<td>Sandoz Pharmaceuticals GmbH Dieselstr. 5 D-70839 Gerlingen</td>
<td>Fluoxetin SANDOZ 20 mg Hartkapseln</td>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Germany</td>
<td>SIEMENS &amp; CO Postfach 1262 D-56119 Bad Ems</td>
<td>Fluoxetin HEXAL 10mg Tabs</td>
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<td>Fluox 20 FT</td>
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<td>STADA Arzneimittel AG Stadastr. 2-18 D-61118 Bad Vilbel</td>
<td>Fluoxstad 20 mg Tabletten</td>
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<td>Dispersible tablet</td>
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<td>Stadapharm GmbH Stadastr. 2-18 D-61118 Bad Vilbel</td>
<td>Fluoxetin Stada 20 mg</td>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Stadapharm GmbH Stadastr. 2-18 D-61118 Bad Vilbel</td>
<td>Fluoxetin Stada 20 mg Tabletten</td>
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<td>Dispersible tablet</td>
<td>Oral use</td>
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<td>Germany</td>
<td>TAD Pharma GmbH Postfach 720 D-27457 Cuxhaven</td>
<td>Fluoxetin TAD 20 mg Kapseln</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
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<td>Germany</td>
<td>TEVA Generics GmbH Kandelstr. 10 D-79199 Kirchzarten</td>
<td>Fluoxetin-TEVA 20 mg Kapseln</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Strength</td>
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<td>TEVA Generics GmbH Kandelstr. 10 D-79199 Kirchzarten</td>
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<td>TEVA Generics GmbH Kandelstr. 10 D-79199 Kirchzarten</td>
<td>Fluoxetin-TEVA 20 mg Tabletten</td>
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<td>Germany</td>
<td>Winthrop Arzneimittel GmbH Industriestr. 10 D-82256 Fuerstenfeldbruck</td>
<td>FluoxeLich 20 mg Kapseln</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Germany</td>
<td>Woerwag Pharma GmbH &amp; Co. KG Postfach 2129 D-71011 Boeblingen</td>
<td>Fluoxgamma 20</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Greece</td>
<td>ANFARM HELLAS AE K.Paleologou&amp; Perikleous 27 15232 Halandri, Greece</td>
<td>FLONITAL</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>ALLERTEC HELLAS AE, 20 Phaethonos, 55132 N.Krini Thessaloniki, Greece</td>
<td>SOFELIN</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>ANTOR EPE, 4 Omirou Street, Maroussi Attikis 15126, Greece</td>
<td>FLUXADIR</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Greece</td>
<td>BIOMEDICA-CHEMICA AE, 25 G.LYRA 14564 K.Kifissia, Greece</td>
<td>EXOSTREPT</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>BROS, Avgis &amp; Galinis 15, 14564 N.kifissia, Greece</td>
<td>STEPHADILAT-S</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>BROS, Avgis &amp; Galinis 15, 14564 N.kifissia, Greece</td>
<td>STEPHADILAT-S</td>
<td>20mg/5ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>FARAN, Ahaias &amp; trizinias, 14564 N.Kifissia, Greece</td>
<td>STRESSLESS</td>
<td>20mg/5ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>FARMASERV LILLY, 15 Km National Road, Athinon-Lamias, 14564 Kifissia, Greece</td>
<td>LADOSE</td>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>FARMASERV LILLY, 15 Km National Road, Athinon-Lamias, 14564 Kifissia, Greece</td>
<td>LADOSE</td>
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<td>Oral solution</td>
<td>Oral use</td>
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<td>FARMASERV LILLY, 15 Km National Road, Athinon-Lamias, 14564 Kifissia, Greece</td>
<td>LADOSE</td>
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<td>Dispersible tablet</td>
<td>Oral use</td>
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<td>Invented Name</td>
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<td>FARMASERV LILLY, 15 Km National Road, Athinon-Lamias, 14564 Kifissia, Greece</td>
<td>LADOSE WEEKLY</td>
<td>90mg</td>
<td>Gastro-resistant capsule hard</td>
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<td>Greece</td>
<td>FARMEDIA AE, 2 B Aigaiou Pelagous, 15343 Agia Paraskevi, Greece</td>
<td>THIRAMIL</td>
<td>20mg/5ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>Greece</td>
<td>GENERICS PHARMA HELLAS 577a Vouliagmenis Av 16451 Argyroupoli, Greece</td>
<td>FLUOXETINE/ GENERICS</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>HELP, 4 Valaoritou, 14452 Metamorfosi Attikis, Greece</td>
<td>SARTUZIN</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>KLEVA, 189 Parnithos, 13671 Aharne Attikis, Greece</td>
<td>FLUOCALM</td>
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<td>Oral solution</td>
<td>Oral use</td>
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<td>NOVARTIS HELLAS, 12 Km National Road Athinon-Lamias, 14410 Metamorfosi, Greece</td>
<td>HAPILUX</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>NOVEXAL HELLAS, Agiou Dimitriou 25, 17455 Kalamaki, Greece</td>
<td>FLUOXETINE/ NOVEXAL</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
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<td>PHARMABRAND AEBE, 15 Km National Road Athinon-Lamias, 14510 Kifissia, Greece</td>
<td>FONZAC</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>PHARMABRAND AEBE, 15 Km National Road Athinon-Lamias, 14510 Kifissia, Greece</td>
<td>FONZAC</td>
<td>20mg/5ml</td>
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<td>PHARMACYPRIA HELLAS, 6 Paster, 11521 Ampelokipi Athens, Greece</td>
<td>DAGRILAN</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>PHARMATEN, 6 Dervenakion, 15351 Pallini Attikis, Greece</td>
<td>DINALEXIN</td>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>RAFARM AEBEE, Kapodistriou &amp; Korinthou 12, 15451 N.Psyhiko, Greece</td>
<td>FOKESTON</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Greece</td>
<td>RAFARM AEBEE, Kapodistriou &amp; Korinthou 12, 15451 N.Psyhiko, Greece</td>
<td>FOKESTON</td>
<td>20mg/5ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>Greece</td>
<td>REMEDINA, 25 Gounari &amp; Areos, 13451 Kamatero Attikis, Greece</td>
<td>ORTHON</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>UNI-PHARMA AEBE, 14 Km National Road Athinon-Lamias, 14564 K.kifissia, Greece</td>
<td>ZINOVAT</td>
<td>20mg/5ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>Greece</td>
<td>UNI-PHARMA AEBE, 14 Km National Road Athinon-Lamias, 14564 K.kifissia, Greece</td>
<td>ZINOVAT</td>
<td>20mg/5ml vial</td>
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<td>Oral use</td>
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<td>ZINOVAT</td>
<td>20mg</td>
<td>Effervescent tablet</td>
<td>Oral use</td>
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<td>UNI-PHARMA AEBE, 14 Km National Road Athinon-Lamias, 14564 K.kifissia, Greece</td>
<td>ZINOVAT</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Apotex Europe Ltd., Rowan House, 41 London Street, UK-RG1 4PS Berkshire,</td>
<td>APO-FLUOXETIN 20 mg kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Hungary</td>
<td>Chinoin, Tő u. 1-5, 1045 Budapest, Hungary.</td>
<td>FLUOXETIN-CHINOIN 20 mg kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Hungary</td>
<td>EGIS Gyógyszergyár Rt., Keresztúri út 30-38, 1106 Budapest, Hungary</td>
<td>FLOXET 10 mg kapszula</td>
<td>10 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<tr>
<td>Hungary</td>
<td>EGIS Gyógyszerágyár Rt., Keresztúri út 30-38, 1106 Budapest, Hungary</td>
<td>FLOXET 20 mg kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>EGIS Gyógyszerágyár Rt., Keresztúri út 30-38, 1106 Budapest, Hungary</td>
<td>FLOXET oldat</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>Humanpharma Gyógyszergyártó Kft. Táncsics Mihály út 82, H-2100 Gödöllő, Hungary</td>
<td>HUMA-FLUOXETIN 20 mg kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>Lek Pharmaceuticals d.d., Verevskova 57, Ljubljana, 1526, Slovenia</td>
<td>PORTAL 20 mg kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>Lilly Hungary Kft., Madách Imre út 13-15. VII. Em, 1075 Budapest, Hungary</td>
<td>PROZAC 20 mg kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>Lilly Hungary Kft., Madách Imre út 13-15. VII. Em, 1075 Budapest, Hungary</td>
<td>PROZAC 20 mg/5 ml oldat</td>
<td>20 mg/5 ml</td>
<td>Oral solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>Richter Gedeon Rt., Győmrői út 19-21, 1103 Budapest, Hungary</td>
<td>DEPREXIN kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Hungary</td>
<td>Sandoz GmbH, Biochemiestrasse 10 A-6250 Kundl, Austria</td>
<td>HAPILUX 20 mg kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Hungary</td>
<td>Teva Gyógyszergyár Rt., Pallagi útca 13, Debrecen, Hungary</td>
<td>FEFLUZIN kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Hungary</td>
<td>Teva Gyógyszergyár Rt., Pallagi útca 13, Debrecen, Hungary</td>
<td>FLUOXETINE-B kapszula</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Actavis hf., Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland</td>
<td>Flúoxetín Actavis</td>
<td>4 mg/ml</td>
<td>Oral liquid</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Actavis hf., Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland</td>
<td>Flúoxetín Actavis</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Actavis hf., Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland</td>
<td>Seról</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Actavis hf., Reykjavíkurvegur 76-78, 220 Hafnarfjörður, Iceland</td>
<td>Seról</td>
<td>10 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Iceland</td>
<td>Generics UK Ltd., Albany Gate Darkes Lane, Potters Bar Herts EN6 1AG, England</td>
<td>Fluoxetine NM Pharma</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Eli Lilly Danmark A/S, Nybrovej 10, 2800 Lyngby, Danmark.</td>
<td>Fontex</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Eli Lilly Danmark A/S, Nybrovej 10, 2800 Lyngby, Danmark.</td>
<td>Fontex</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Eli Lilly Danmark A/S, Nybrovej 10, 2800 Lyngby, Danmark.</td>
<td>Fontex</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Iceland</td>
<td>Eli Lilly Danmark A/S, Nybrovej 10, 2800 Lyngby, Danmark.</td>
<td>Fluoxin</td>
<td>20 mg</td>
<td>Soluble tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Ireland</td>
<td>Clonmel Healthcare Limited Waterford Road, Clonmel, Co. Tipperary, Ireland</td>
<td>Prozamel</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Ireland</td>
<td>Eli Lilly and Company Limited Kingsclere Road Basingstoke Hampshire, RG21 6XA , UK</td>
<td>Prozac</td>
<td>20 mg/mg</td>
<td>Oral solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Ireland</td>
<td>Eli Lilly and Company Limited Kingsclere Road  Basingstoke Hampshire, RG21 6XA , UK</td>
<td>Prozac</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Ireland</td>
<td>Eli Lilly and Company Limited Kingsclere Road  Basingstoke Hampshire, RG21 6XA , UK</td>
<td>Prozac</td>
<td>60 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Ireland</td>
<td>Eli Lilly and Company Limited Kingsclere Road  Basingstoke Hampshire, RG21 6XA , UK</td>
<td>Prozac</td>
<td>90 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Ireland</td>
<td>Fujisawa Deutschland GmbH  Berg-am-Laim Str. 129, D-81673 Munchen, Germany</td>
<td>Affex</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Ireland</td>
<td>Generics (UK) Limited, 12 Station Close, Potters Bar  Hertfordshire, EN6 1TL , UK</td>
<td>Gerozac</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Ireland</td>
<td>Niche Generics Limited, 1 The Cam Centre, Wilbury Way, Hertfordshire, SG4 0TW, UK</td>
<td>Biozac &amp; Prozit</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Ireland</td>
<td>Ranbaxy Ireland Limited, Cork Road, Cashel, Co. Tipperary, Ireland</td>
<td>Ranbaxy</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Ireland</td>
<td>Ratiopharm GmbH, Graf-Arco-Str. 3, 89079 Ulm, Germany</td>
<td>Fluoxetine</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Ireland</td>
<td>Stada Arzneimittel AG Stadastrasse 2-18, D-61118 Bad Vilbel, Germany</td>
<td>Prozatan</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>A. Menarini Industrie Farmaceutiche Riunite S.r.l. Via Sette Santi, 3 - 50131 Firenze Italy</td>
<td>Fluoxeren</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>A. Menarini Industrie Farmaceutiche Riunite S.r.l. Via Sette Santi, 3 - 50131 Firenze Italy</td>
<td>Fluoxeren</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>A. Menarini Industrie Farmaceutiche Riunite S.r.l. Via Sette Santi, 3 - 50131 Firenze Italy</td>
<td>Fluoxeren</td>
<td>20 mg</td>
<td>Soluble tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Benedetti S.p.A. Vicolo de' Bacchettoni, 1 51100 Pistoia Italy</td>
<td>Fluoxetina</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Italy</td>
<td>Benedetti S.p.A. Vicolo de' Bacchettoni, 1 51100 Pistoia Italy</td>
<td>Zafluox</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Bioprogress S.p.A. Industria Chimico Farmaceutica, Via Aurelia 58, 00165 ROMA, Italy</td>
<td>Biofloxoral</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Bioprogress S.p.A. Industria Chimico Farmaceutica, Via Aurelia 58, 00165 ROMA, Italy</td>
<td>Biofloxoral</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Italy</td>
<td>Bioprogress S.p.A. Industria Chimico Farmaceutica, Via Aurelia 58, 00165 ROMA, Italy</td>
<td>Biofloxoral</td>
<td>20 mg</td>
<td>Soluble tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Biore Italia S.r.l. Via V. Grassi, 13 00155 ROMA, Italy</td>
<td>Fluoxin</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>Biore Italia S.r.l. Via V. Grassi, 13 00155 ROMA, Italy</td>
<td>Fluoxin</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>Doc Geenrici S.r.l. Via Manuzio, 7 20124 Milano Italy</td>
<td>Fluoxetina Doc</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<tr>
<td>Italy</td>
<td>Doc Geenrici S.r.l. Via Manuzio, 7 20124 Milano Italy</td>
<td>Fluoxetina Doc</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>DOROM S.r.l., Via Volturno 48, Quinto de Stampi-Rozzano, 20089 Milano, Italy</td>
<td>Fluoxetina Dorom</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>EG S.p.A. Via Domenico Scarlatti, 31 20124 Milano Italy</td>
<td>Fluoxetina EG</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>EG S.p.A. Via Domenico Scarlatti, 31 20124 Milano Italy</td>
<td>Fluoxetina EG</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>EG S.p.A. Via Domenico Scarlatti, 31 20124 Milano Italy</td>
<td>Fluoxetina EG</td>
<td>20 mg</td>
<td>Soluble tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Eli Lilly Italia S.p.A. Via Gramsci, 731/733 50019 Sesto Fiorentino - Firenze Italy</td>
<td>Prozac</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Italy</td>
<td>Eli Lilly Italia S.p.A. Via Gramsci, 731/733 50019 Sesto Fiorentino - Firenze Italy</td>
<td>Prozac</td>
<td>20 mg</td>
<td>Soluble tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
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<td>Eli Lilly Italia S.p.A. Via Gramsci, 731/733 50019 Sesto Fiorentino - Firenze Italy</td>
<td>Prozac FD</td>
<td>20 mg</td>
<td>Soluble tablet</td>
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<td>Italy</td>
<td>F.I.R.M.A. S.p.A. Via di Scandicci, 37 50143 Firenze Italy</td>
<td>Proxerene</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>F.I.R.M.A. S.p.A. Via di Scandicci, 37 50143 Firenze Italy</td>
<td>Proxerene</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>Farma Uno S.r.l. VIA CONFORTI, 42 CASTEL SAN GIORGIO - SA 84083 Italy</td>
<td>Clexiclor</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Italy</td>
<td>Farma Uno S.r.l. VIA CONFORTI, 42 CASTEL SAN GIORGIO - SA 84083 Italy</td>
<td>Clexiclor</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<td>Italy</td>
<td>Farma Uno S.r.l. VIA CONFORTI, 42 CASTEL SAN GIORGIO - SA 84083 Italy</td>
<td>Clexiclor</td>
<td>20 mg</td>
<td>Soluble tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme - Padova Italy</td>
<td>Fluoxetina</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme - Padova Italy</td>
<td>Fluoxetina</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>Italy</td>
<td>Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme - Padova Italy</td>
<td>Fluoxetina Fidia</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Italy</td>
<td>Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme - Padova Italy</td>
<td>Fluoxetina Fidia</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme - Padova Italy</td>
<td>Fluoxetina Fidia</td>
<td>20 mg</td>
<td>Soluble tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Get S.r.l. Via Dante Alighieri, 63 Abano Terme 35031 Padova Italy</td>
<td>Fluoxetina Get</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Italy</td>
<td>Get S.r.l. Via Dante Alighieri, 63 Abano Terme 35031 Padova Italy</td>
<td>Fluoxetina Get</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>Hexal S.p.A. Via Paracelso, 16 20041 Agrate Brianza - Milano Italy</td>
<td>Fluoxetina</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
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<td>Hexal S.p.A. Via Paracelso, 16 20041 Agrate Brianza - Milano Italy</td>
<td>Fluoxetina Hexal</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Italy</td>
<td>IPSO Pharma S.r.l. Via San Rocco, 6 85033 Episcopia - Potenza Italy</td>
<td>Ipsumor</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>IPSO Pharma S.r.l. Via San Rocco, 6 85033 Episcopia - Potenza Italy</td>
<td>Ipsumor</td>
<td>20 mg</td>
<td>Soluble tablet</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>ISTITUTO BIOCHIMICO ITALIANO GIOVANNI LORENZINI SPA Via Tucidide, 56 torre 6 20134 Milano Italy</td>
<td>Ibixetin</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
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<td>ISTITUTO BIOCHIMICO ITALIANO GIOVANNI LORENZINI SPA Via Tucidide, 56 torre 6 20134 Milano Italy</td>
<td>Ibixetin</td>
<td>4 mg/ml</td>
<td>Oral drops, solution</td>
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<td>Italy</td>
<td>ISTITUTO BIOCHIMICO ITALIANO GIOVANNI LORENZINI SPA Via Tucidide, 56 torre 6 20134 Milano Italy</td>
<td>Ibixetin</td>
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<td>Oral use</td>
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<td>Vecchi &amp; Piam S.a.p.a. Via Padre G. Semeria, 5 16131 Genova Italy</td>
<td>Lisemir</td>
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<td>Chemical Works of Gedeon Richter Ltd, Gyömrői út 19-21 H - 1103 Budapest HUNGARY</td>
<td>Framex</td>
<td>20 mg</td>
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<td>Egis Pharmaceuticals, Kereszturi ut 30-38 H-1106 Budapest HUNGARY</td>
<td>Floxet</td>
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<td>Flux 20</td>
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<td>Fluval</td>
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<td>Magrilan</td>
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<td>Lithuania</td>
<td>KRKA, d.d., Novo mesto, Smarjeska c.6, 8501 Novo mesto, Slovenia</td>
<td>Fluval</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Lannacher Heilmittel Ges.m.b.H., Schlossplatz 1, A-8502 Lannach, Austria</td>
<td>Fluoxetine Lannacher</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Latvian JSC Grindeks, Krustpils ul. 53, Riga, LV-1057 Latvia</td>
<td>Deprimaks</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Lek Pharmaceuticals d.d., Verovskova 57, 1526 Ljublana, Slovenia</td>
<td>Portal capsules 20 mg</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Lithuania</td>
<td>Medochemie Ltd., p.o. box 51409, Limassol, CY - 3505, Constantinoupolcos Str., 3011 Limassol, Cyprus</td>
<td>Magrilan</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<tr>
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<td>Lithuania</td>
<td>Nycomed SEFA AS, Jaama 55B, 63308 Polva, Estonia</td>
<td>Nycoflox</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Lithuania</td>
<td>Slovakofarma, Nitrianka 100, 920 27 Hlohovec, Slovakia</td>
<td>Deprenon</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>DOCPHARMA N.V., Ambachtenlaan 13 H, B-3001 Heverlee, Belgium</td>
<td>Docfluoxetine</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>ELI LILLY BENELUX S.A. Rue de l'Etuve 52 1000 Bruxelles, Belgium</td>
<td>Prozac</td>
<td>20 mg</td>
<td>Powder</td>
<td>Oral use</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>ELI LILLY BENELUX S.A. Rue de l'Etuve 52 1000 Bruxelles, Belgium</td>
<td>Prozac</td>
<td>20mg/5ml</td>
<td>Oral solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>ELI LILLY BENELUX S.A. Rue de l'Etuve 52 1000 Bruxelles, Belgium</td>
<td>Prozac</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<tr>
<td>Luxembourg</td>
<td>ELI LILLY BENELUX S.A. Rue de l'Etuve 52, 1000 Bruxelles, Belgium</td>
<td>Fontex</td>
<td>20 mg</td>
<td>Powder</td>
<td>Oral use</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>ELI LILLY BENELUX S.A. Rue de l'Etuve 52, 1000 Bruxelles, Belgium</td>
<td>Fontex Dispersible</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>MERCK N.V., Brusselsesteenweg 288, B-3090 Overijse, Belgium</td>
<td>Merck Fluoxetine</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>S.M.B. Laboratories, 26-28 Rue de la Pastorale, B-1080 Bruxelles, Belgium</td>
<td>Fluoxone Divule</td>
<td>20 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>SOCOBOM N.V. Louisalaan 149/24 B-1050 Brussel, Belgium</td>
<td>Fluox</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Malta</td>
<td>Actavis hf, 3 Reykjavikurvegi 78 220 Hafnarfjörður Iceland</td>
<td>Fluoxetin Delta</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Malta</td>
<td>AEGIS Ltd, 1 Efferpis Street, 2003 Nicosia, Cyprus</td>
<td>Fluxil</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
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<td>Member State</td>
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<tr>
<td>Malta</td>
<td>Anfarm Hellas SA, 27, K. Paleologou &amp; Perikleous, Halandri, 15232, Athens, Greece</td>
<td>Flonital</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Malta</td>
<td>Eli Lilly and Co Ltd, Kingslere Road, Basingstoke, RG21 6XA, Hampshire, UK</td>
<td>Prozac</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Malta</td>
<td>Eli Lilly and Co Ltd, Kingslere Road, Basingstoke, RG21 6XA, Hampshire, UK</td>
<td>Prozac Weekly</td>
<td>90mg</td>
<td>Modified-release capsule, hard</td>
<td>Oral use</td>
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<tr>
<td>Malta</td>
<td>Medochemie, 1 - 10 Constantinopleos Street, 3011, Limasol, Cyprus</td>
<td>Magrilan</td>
<td>20mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Malta</td>
<td>Mepha Ltd, Rua Elias Garcia No 28, C Edificio 4, Venda Nova, 2701 355, Amadora, Portugal</td>
<td>Salipax</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Malta</td>
<td>Schein Pharm, Benham Valence, Newbury, RG20 8LU, Berkshire, UK</td>
<td>Oxactin</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Alpharma B.V., Postbus 313, NL-3740 AH Baarn</td>
<td>Fluroxetin Dumex 20 mg, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
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<td>Member State</td>
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<tr>
<td>Netherlands</td>
<td>Apothecon B.V., Postbus 324, NL-3770 AH Barneveld</td>
<td>Fluoxetine 20 A, capsules 20 mg</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Apothecon B.V., Postbus 324, NL-3770 AH Barneveld</td>
<td>Fluoxetine 20 A, coated tablets 20 mg</td>
<td>20 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Centrafarm Services B.V., Postbus 289, NL-4870 AG Etten Leur</td>
<td>Fluoxetine CF 20, dispersible tablets 20 mg</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Centrafarm Services B.V., Postbus 289, NL-4870 AG Etten Leur</td>
<td>Fluoxetine CF 20 mg, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Eli Lilly Nederland BV, Postbus 379, NL-3990 GD Houten</td>
<td>Fluoxetine 20, capsules 20 mg</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Eli Lilly Nederland BV, Postbus 379, NL-3990 GD Houten</td>
<td>Prozac capsule, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Eli Lilly Nederland BV, Postbus 379, NL-3990 GD Houten</td>
<td>Prozac drank, oral solution</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<tr>
<td>Netherlands</td>
<td>Eli Lilly Nederland BV, Postbus 379, NL-3990 GD Houten</td>
<td>Prozac dispergeerbare tablet, dispersible tablet</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Eurobase B.V., Mercuriusweg 8 – 10, NL-3771 NC Barneveld</td>
<td>Fluoxetine EB 20, capsules 20 mg</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Genfarma B.V., Postbus 2062, NL-1500 GB Zaandam</td>
<td>Fluoxetine Gf 20 mg, capsules</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Genfarma B.V., Postbus 2062, NL-1500 GB Zaandam</td>
<td>Fluoxetine Gf 20 mg/5 ml, solution 4 mg/ml</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Genfarma B.V., Postbus 2062, NL-1500 GB Zaandam</td>
<td>Fluoxetine Gf 20 mg, tablets</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Genfarma B.V., Postbus 2062, NL-1500 GB Zaandam</td>
<td>Fluoxetine Gf 20 mg/5 ml, oral solution</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>GenRx B.V., Postbus 75, NL-6920 AB Duiven</td>
<td>Fluoxetine 20 mg, tablets</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
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<tr>
<td>Netherlands</td>
<td>Hexal B.V., Postbus 251, NL-2180 AG Hillegom</td>
<td>Fluoxetine 20 mg, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Hexal B.V., Postbus 251, NL-2180 AG Hillegom</td>
<td>Fluoxetine 20 mg, tablets</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Katwijk Farma B.V., Postbus 408, NL-2300 AK Leiden</td>
<td>Fluoxetine 20 mg Katwijk, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Merck Generics BV, Dieselweg 25, NL-3752 LB Bunschoten</td>
<td>Fluoxetine Merck 20 mg, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Niche Generics Ltd. 1 The Cam Centre Wilbury Way SG4 0TW Hitchin, Hertfordshire</td>
<td>Fluoxetine Capsules 20 mg, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Niche Generics Ltd. 1 The Cam Centre Wilbury Way SG4 0TW Hitchin, Hertfordshire</td>
<td>Bioglan Fluoxetine Capsules 20 mg, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Pharmachemie B.V., Postbus 552, NL-2003 RN Haarlem</td>
<td>Fluoxetine 20 PCH, tablets 20 mg</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Netherlands</td>
<td>Pharmachemie B.V., Postbus 552, NL-2003 RN Haarlem</td>
<td>Fluoxetine 20 PCH, capsules 20 mg</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Pharmacin Products B.V., Molenvliet 103, NL-3335 LH Zwijndrecht</td>
<td>Fluoxetine 20 mg, tablets</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<tr>
<td>Netherlands</td>
<td>Sandoz B.V., Postbus 216, NL-1380 AE Weesp</td>
<td>Fluoxetine Sandoz 20, capsules</td>
<td>20 mg</td>
<td>Capsule</td>
<td>Oral use</td>
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<tr>
<td>Netherlands</td>
<td>Sandoz B.V., Postbus 216, NL-1380 AE Weesp</td>
<td>Fluoxetine Sandoz tablet 20, tablets</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Stada Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel</td>
<td>Fluoxstad 20 mg, dispersible tablets</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Stada Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel</td>
<td>Flustad 20 mg, dispersible tablets</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Norway</td>
<td>Eli Lilly Norge AS, Grenseveien 99, P.O.Box 6090 Etterstad, NO-0601 Oslo, Norway</td>
<td>Fontex</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
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<td>Member State</td>
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<tr>
<td>Norway</td>
<td>Farmagon AS, P.O.Box 35, 1332 Østerås, Norway</td>
<td>Fluoxetin Farmagon</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Norway</td>
<td>Merck NM AB, Box 25033, SE-104 35 Stockholm, Sweden</td>
<td>Fluoxetin Merck NM</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Norway</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, DE-89079 Ulm, Germany</td>
<td>Fluoxetin Ratiopharm</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Norway</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, DE-89079 Ulm, Germany</td>
<td>Fluoxetin Ratiopharm</td>
<td>20 mg</td>
<td>Dispersible tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Poland</td>
<td>ANPHARM Przedsiębiorstwo Farmaceutyczne S.A., Annopol 6B, 03-236 Warszawa, Poland</td>
<td>Fluoksetyna</td>
<td>10 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<tr>
<td>Poland</td>
<td>ANPHARM Przedsiębiorstwo Farmaceutyczne S.A., Annopol 6B, 03-236 Warszawa, Poland</td>
<td>Fluoksetyna</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<tr>
<td>Poland</td>
<td>Eli Lilly and Company Ltd. Kingsclere Road, Basingstoke RG216XA Hampshire, UK</td>
<td>Prozac</td>
<td>20 mg</td>
<td>Capsule, soft</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
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<td>Poland</td>
<td>ICN Polfa Rzeszów S.A., ul. Przemysłowa 2, 35-959 Rzeszów, Poland</td>
<td>Deprexetin</td>
<td>20 mg</td>
<td>Capsule, soft</td>
<td>Oral use</td>
</tr>
<tr>
<td>Poland</td>
<td>Kutnowskie Zakłady Farmaceutyczne &quot;Polfa&quot; S.A Sienkiewicza 25 99-300 Kutno, Poland</td>
<td>Andepin</td>
<td>20 mg</td>
<td>Capsule, soft</td>
<td>Oral use</td>
</tr>
<tr>
<td>Poland</td>
<td>Mepha Lda, Rua Elias Garcia, nr 28-C Edificio 4-Venda Nova, 2701-335 Amadora, Portugal</td>
<td>Salipax</td>
<td>20 mg</td>
<td>Capsule, soft</td>
<td>Oral use</td>
</tr>
<tr>
<td>Poland</td>
<td>Ranbaxy (Poland) Sp. z o.o., ul. Kubickiego 11, 02-954 Warszawa, Poland</td>
<td>Xetiran</td>
<td>20 mg</td>
<td>Capsule, soft</td>
<td>Oral use</td>
</tr>
<tr>
<td>Poland</td>
<td>Sanofi-Synthelabo Sp. z o.o. Domaniewska 41, 02-672 Warszawa, Poland</td>
<td>Bioxetin</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Poland</td>
<td>Slovakofarma a.s., ul. Nitrańska 100, 92027 Hlodovac, Slovakia</td>
<td>Deprenon</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
</tr>
<tr>
<td>Poland</td>
<td>Synteza Sp. z o.o. - Przedsiębiorstwo Farmaceutyczno-Chemiczne, ul. Św. Michała 67/71, 61-005 Poznań, Poland</td>
<td>Andepin</td>
<td>20 mg</td>
<td>Capsule, soft</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
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<td>Poland</td>
<td>Zakłady Farmaceutyczne &quot;POLPHARMA&quot; S.A., ul. Pelplińska 19, 83-200 Starogard Gdański, Poland</td>
<td>Fluoxetin</td>
<td>20 mg</td>
<td>Capsule, soft</td>
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<td>Portugal</td>
<td>Alpharma ApS, Rua Virgílio Correia, 11-A 1600-219 Lisboa Portugal</td>
<td>Fluoxetina Alpharma 20 mg Cápsulas</td>
<td>20 mg</td>
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<td>Alter, S.A., Estrada Marco do Grilo - Zemouto 2830 Coimbra Portugal</td>
<td>Fluoxetina Alter 20 mg Cápsulas</td>
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<td>Bexal Produtos Farmacêuticos S.A., Rua Prof. Ricardo Jorge, 5 A - Miraflores 1495-153 Algès Portugal</td>
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<td>Bluepharma - Indústria Farmacêutica, S.A., São Martinho do Bispo 3041-801 Coimbra Portugal</td>
<td>Fluoxetina Bluepharma Indústria Farmacêutica S.A. 20 mg cápsulas</td>
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<td>Ciclum Farma Unipessoal, Lda., Rua Alfredo da Silva, nº 16 2610-016 Amadora Portugal</td>
<td>Fluoxetina Ciclum 20 mg Cápsulas</td>
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<td>Portugal</td>
<td>Cinfa Portugal, Lda., Av. Tomás Ribeiro, 43 - Bloco 2, 3º F - Edifício Neopark 2790-221 Carnaxide Portugal</td>
<td>Fluoxetina Cinfa 20 mg Cápsulas</td>
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<td>Route of administration</td>
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<td>Euro-Labor, Laboratórios de Síntese Química e Especialidades Farmacêuticas, S.A., Rua Alfredo da Silva, nº 16 2720-028 Amadora Portugal</td>
<td>Fluoxetine Nodepe 20 mg cápsulas</td>
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<td>Euro-Labor, Laboratórios de Síntese Química e Especialidades Farmacêuticas, S.A., Rua Alfredo da Silva, nº 16 2720-028 Amadora Portugal</td>
<td>Nodepe 4 mg/ml Oral solution</td>
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<td>Farma APS - Produtos Farmacêuticos, S.A., Rua José Galhardo nº 3, loja 3 - c/v 1750-131 Lisboa Portugal</td>
<td>Fluoxetine Fluxin 20 mg Cápsulas</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Farma APS - Produtos Farmacêuticos, S.A., Rua José Galhardo nº 3, loja 3 - c/v 1750-131 Lisboa Portugal</td>
<td>Fluoxetine Fluxin 4 mg/ml Solução Oral</td>
<td>4 mg/ml</td>
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<td>Farmoquímica Baldacci, S.A., Rua Duarte Galvão, n.º 44 1549-005 Lisboa Portugal</td>
<td>Tuneluz</td>
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<td>Farmoz - Sociedade Técnico-Medicinal, S.A., Rua Prof. Henrique de Barros, Edificio Sagres, 3ºA 2685-338 Prior Velho Portugal</td>
<td>Fluoxetine Farmoz 20 mg Cápsulas</td>
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<td>Generis Farmacêutica, S.A., Rua José Galhardo, n.º 3 1750-131 Lisboa Portugal</td>
<td>Fluoxetina Generis 20 mg Cápsulas</td>
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<td>Portugal</td>
<td>Generis Farmacêutica, S.A., Rua José Galhardo, n.º 3 1750-131 Lisboa Portugal</td>
<td>Fluoxetina Generis 20 mg/5 ml Solução Oral</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>Portugal</td>
<td>Germed Farmacêutica, Lda., Edifício Monsanto - Rua Alto do Montijo, 13 - 1º Dto. 2790-012 Portela de Carnaxide Portugal</td>
<td>Fluoxetina Germed 20 mg cápsula</td>
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<td>Hikma Farmacêutica (Portugal), Lda., Estrada do Rio da Mó, nº 8 - 8 A e 8 B - Fervença 2705-906 Terrugem (SNT) Portugal</td>
<td>Fluoxetina Hikma 20 mg Cápsulas Duras</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Portugal</td>
<td>Irex - Promoção e Comercialização de Produtos Farmacêuticos, Lda., Empreendimento Lagoas Park - Edifício 7, 2º e 3º andar 2740-244 Porto Salvo Portugal</td>
<td>Fluoxetina Irex 20 mg Cápsulas</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>ITF Farma - Produtos Farmacêuticos, Lda., Rua Consigliere Pedroso, 123 - Queluz de Baixo 2745-557 Barcarena Portugal</td>
<td>Fluoxetina ITF 20 mg Cápsulas</td>
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<td>Labesfal - Laboratórios Almiro, S.A., 3465-051 Campo de Besteiros Portugal</td>
<td>Fluoxetina Flomex 20 mg Cápsulas</td>
<td>20 mg</td>
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<td>Labesfal - Laboratórios Almiro, S.A., 3465-051 Campo de Besteiros Portugal</td>
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<td>Labesfal - Laboratórios Almiro, S.A., 3465-051 Campo de Besteiros Portugal</td>
<td>Mizac</td>
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<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Laboratório B. A. Farma, Lda., Rua Prof. Sousa da Câmara, 207-211 1074-803 Lisboa Portugal</td>
<td>Selectus</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Portugal</td>
<td>Laboratórios Vitória, S.A., Rua Elias Garcia, nº 28 - Venda Nova 2700-327 Amadora Portugal</td>
<td>Digassim</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Portugal</td>
<td>Laboratórios Vitória, S.A., Rua Elias Garcia, nº 28 - Venda Nova 2700-327 Amadora Portugal</td>
<td>Digassim Durapac 90 mg cápsulas duras gastro-resistentes</td>
<td>90 mg</td>
<td>Gastro-resistant capsule, hard</td>
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<td>Lacer, S.A., Calle Sardenya, 350 E-08025 Barcelona Espanha</td>
<td>Deborax 20 mg Cápsulas</td>
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<td>Capsule, hard</td>
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<td>Lilly Farma - Produtos Farmacêuticos, Lda., Rua Dr. António Loureiro Borges, nº 4 - Piso 3 - Arquiparque - Miraflores 1495-131 Algés Portugal</td>
<td>Prozac</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>Prozac</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Prozac Durapac 90 mg Cápsulas Duras Gastro-Resistentes</td>
<td>90 mg</td>
<td>Gastro-resistant capsule, hard</td>
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<td>Medicamed - Produtos Médicos e Farmacêuticos, S.A., Edifício Olympus - Avenida D. Afonso Henriques, 1462 4450-013 Matosinhos Portugal</td>
<td>Fluoxetina Medicamed</td>
<td>20 mg</td>
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<td>Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda., Rua Elias Garcia, nº 28 - C, Edifício 4 - Venda Nova 2701-355 Amadora Portugal</td>
<td>Fluoxetina Mepha 20 mg Cápsulas</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Mepha - Investigação, Desenvolvimento e Fabricação Farmacêutica, Lda., Rua Elias Garcia, nº 28 - C, Edifício 4 - Venda Nova 2701-355 Amadora Portugal</td>
<td>Fluoxetina Salipax 20 mg Cápsulas</td>
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<td>Merck Genéricos - Produtos Farmacêuticos, Lda., Rua Alfredo da Silva, 3 - C - 4º 1300-040 Lisboa Portugal</td>
<td>Fluoxetina Merck Genéricos 20 mg Cápsulas</td>
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<td>Psipax</td>
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<td>Prodome - Companhia Portuguesa de Genéricos, Lda., Rua Gomes Freire, n.º 9-A 1150-175 Lisboa Portugal</td>
<td>Fluoxetina Prodome 20 mg Cápsulas</td>
<td>20 mg</td>
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<td>Prodome - Companhia Portuguesa de Genéricos, Lda., Rua Gomes Freire, n.º 9-A 1150-175 Lisboa Portugal</td>
<td>Fluoxetina Prodome 20 mg/5 ml Solução Oral</td>
<td>4 mg/ml</td>
<td>Oral solution</td>
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<td>Ratiopharm - Comércio e Indústria de Produtos Farmacêuticos, Lda., Edifício Tejo - 6º Piso - Rua Quinta do Pinheiro 2790-143 Carnaxide Portugal</td>
<td>Fluoxetina Ratiopharm 20 mg Cápsulas</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Portugal</td>
<td>Sandoz GmbH, Biochemiestrasse, 10 A-6250 Kundl Áustria</td>
<td>Fluoxetina Sandoz 20 mg Cápsulas</td>
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<td>Fluoxetina Stada</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Seroliber</td>
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<td>Teva Pharma, B.V., Industrieweg, 23 NL-3640 AE Mijdrecht Holanda</td>
<td>Fluoxetine Teva 20 mg cápsulas</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Portugal</td>
<td>toLife - Produtos Farmacêuticos, S.A., Estrada Consiglieri Pedroso nº 71, Edifício B 1ª - Queluz de Baixo 2730-055 Barcarena Portugal</td>
<td>Fluoxetine toLife 20 mg cápsulas</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Portugal</td>
<td>Vetiquima - Produtos Químicos, Lda. Estrada Nacional 10, Km 140,260 2696-901 Bobadela Portugal</td>
<td>Fluoxetine Lusocampo 20 mg Cápsulas</td>
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<td>Capsule, hard</td>
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<td>Slovak Republic</td>
<td>EGIS Pharmaceuticals Ltd., Keresztúri út 30-38, HU - 1160 Budapest</td>
<td>FLOXET 10mg</td>
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<td>Slovak Republic</td>
<td>Eli Lilly Export S.A. 16, Chemin de Coquelicots CH - 1214 Geneva</td>
<td>PROZAC</td>
<td>20mg</td>
<td>Capsule</td>
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<td>Slovak Republic</td>
<td>Krka d.d., Šmarješka cesta 6, SL - 850 01 Novo Mesto</td>
<td>FLUVAL 20mg</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Slovak Republic</td>
<td>Medochemie Ltd., 1-10 Constantinoupolos Str., P.O.Box 51409 Limassol, CY - 3505 Cyprus</td>
<td>MAGRILAN 20mg</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Slovak Republic</td>
<td>Sandoz GmbH, Biochemiestrasse 10, A - 6250 Kundl</td>
<td>HAPILUX 20mg</td>
<td>20mg</td>
<td>Capsule, hard</td>
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<td>Slovak Republic</td>
<td>Zentiva a.s., U Kabelovny 130, Dolní Mecholupy, CZ - 102 37 Praha 10</td>
<td>DEPRENON</td>
<td>20mg</td>
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<td>Oral use</td>
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<td>Zentiva a.s., U Kabelovny 130, Dolní Mecholupy, CZ - 102 37 Praha 10</td>
<td>DEPRENON ZENTIVA</td>
<td>20mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Slovenia</td>
<td>Eli Lilly Holdings Limited, Kingsclere Road, Basinstoke, Hampshire RG21 6XA, Great Britain</td>
<td>PROZAC</td>
<td>20 mg/5 ml</td>
<td>Oral solution</td>
<td>Oral use</td>
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<td>Slovenia</td>
<td>Eli Lilly Holdings Limited, Kingsclere Road, Basinstoke, Hampshire RG21 6XA, Great Britain</td>
<td>PROZAC</td>
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<td>Capsule, hard</td>
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<td>Slovenia</td>
<td>KRKA, tovarna zdravil, d.d., Novo mesto, Šmarješka cesta 6, SI-8501 Novo mesto, Slovenia</td>
<td>FLUVAL</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Slovenia</td>
<td>LEK farmacevtska družba d.d., Verovškova 57, SI-1526 Ljubljana, Slovenia</td>
<td>PORTAL</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Slovenia</td>
<td>Medis, Podjetje za proizvodnjo in trženje d.o.o., Brnčičeva 1, SI-1001 Ljubljana, Slovenia</td>
<td>SALIPAX</td>
<td>20 mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Spain</td>
<td>ALACAN S.A., Capricornio, 5, Alicante, Spain</td>
<td>FLUOXETINA ALACAN 20 mg hard capsules</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Spain</td>
<td>BEXAL FARMACEUTICA, S.A, Ventura Rodriguez, 7 - 5ª planta, Madrid 28008, Spain</td>
<td>FLUOXETINA BEXAL 20 mg hard capsules</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>CENINTER S.A., Juan Ignacio Luca de Tena, 8, Madrid 28027, Spain</td>
<td>FLUOXETINA CENINTER 20 mg hard capsules</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>Spain</td>
<td>COMBINO PHARM, S.L., Fructuos Gelabert, 6-8, Sant Joan Despi 08970, Spain</td>
<td>FLUOXETINA COMBINO PHARM 20 mg hard capsules</td>
<td>20 mg</td>
<td>Capsule, hard</td>
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<td>NODEPE 20 mg capsules (Spain CMS)</td>
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<td>LABORATORIOS BELMAC, S.A., Teide, 4-planta baja. Poligono Empresarial La Marina, San Sebastian de los Reyes 28700, Spain</td>
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<td>FLUOXETINA ESTEVE 20 mg hard capsules</td>
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<td>Capsule, hard</td>
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<td>FLUOXETINA TEVA</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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**FLUOXAMINE containing medicinal products with Marketing Authorisation in the European Union**

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<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Greece</td>
<td>SOLVAY PHARMA, 63 Agiou Dimitriou 17456 Alimos, Greece</td>
<td>DUMYROX</td>
<td>100mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Solvay Pharmaceuticals B.V.NL-1381 CP Weesp, C.J. van Houtenlaan 36. /8121AA Olst, Veerweg 12. The Netherlands</td>
<td>FEVARIN 50 mg filmtabletta</td>
<td>50 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Hungary</td>
<td>Solvay Pharmaceuticals B.V.NL-1381 CP Weesp, C.J. van Houtenlaan 36. /8121AA Olst, Veerweg 12. The Netherlands</td>
<td>FEVARIN 100 mg filmtabletta</td>
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<td>Ireland</td>
<td>Solvay Healthcare Limited Mansbridge Road, West End Southampton, SO18 3JD, UK</td>
<td>Faverin</td>
<td>50 mg</td>
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<td>Solvay Healthcare Limited Mansbridge Road, West End Southampton, SO18 3JD, UK</td>
<td>Faverin</td>
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<td>Italy</td>
<td>Schering Plough S.p.A. Via Ripamonti, 89 20141 Milano Italy</td>
<td>Maveral</td>
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<td>Schering Plough S.p.A. Via Ripamonti, 89 20141 Milano Italy</td>
<td>Maveral</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Film-coated tablet</td>
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<td>tablets</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Solvay Pharmaceuticals B.V., [P.O.Box 900 NL - 1380 DA Weesp] C.J. van Houtenlaan 36 NL - 1381 CP Weesp THE NETHERLANDS</td>
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<td>50 mg</td>
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<td>Latvia</td>
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<td>Oral use</td>
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<td>100 mg</td>
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<td>Luxembourg</td>
<td>SANDOZ S.A., Telecom Gardens, Medialaan 40, B-1800 Vilvoorde, Belgium</td>
<td>Fluvoxamine Sandoz</td>
<td>100 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Luxembourg</td>
<td>SOLVAY PHARMA, 3 Avenue du Bourgmestre, E. Demunter, B-1090 Bruxelles, Belgium</td>
<td>Floxyfral</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Malta</td>
<td>Solvay Pharm BV, CJ Van Hountenlaan 36, 1381, CP Weesp, The Netherlands</td>
<td>Faverin</td>
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<td>Oral use</td>
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<td>Malta</td>
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<td>Faverin</td>
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<td>Oral use</td>
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<td>Netherlands</td>
<td>Alpharma B.V., Postbus 313, NL-3740 AH Baarn</td>
<td>Fluvoxaminemaleaat Dumex 50 mg, tablets</td>
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<td>Netherlands</td>
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<td>Centrafarm Services B.V., Postbus 289, NL-4870 AG Etten Leur</td>
<td>Fluvoxaminemaleaat CF 50 mg, tablets</td>
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<td>Member State</td>
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<td>Invented Name</td>
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<td>Fluvoxaminemaleaat CF 100 mg, tablets</td>
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<td>Oral use</td>
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<td>Netherlands</td>
<td>Eurobase B.V., Mercuriusweg 8 – 10, NL-3771 NC Barneveld</td>
<td>Fluvoxamine maleaat EB 50 mg, tablets</td>
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<td>Genfarma B.V., Postbus 2062, NL-1500 GB Zaandam</td>
<td>Fluvoxaminemaleaat Gf 50 mg, tablets</td>
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<td>Netherlands</td>
<td>Genthon B.V., Postbus 7071, NL-6503 GN Nijmegen</td>
<td>Fluvoxaminemaleaat 25 mg, tablets</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Oral use</td>
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<td>Netherlands</td>
<td>Hexal AG, Postfach 1263, D-83602 Holzkirchen</td>
<td>Fluvoxaminemaleaat 50 mg, coated tablets</td>
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<td>Oral use</td>
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<td>Netherlands</td>
<td>Hexal AG, Postfach 1263, D-83602 Holzkirchen</td>
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<td>Fluvoxaminemaleaat 50 mg Katwijk, tablets</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Katwijk Farma B.V., Postbus 408, NL-2300 AK Leiden</td>
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<td>Oral use</td>
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<td>Netherlands</td>
<td>Merck Generics BV, Dieselweg 25, NL-3752 LB Bunschoten</td>
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<td>Merck Generics BV, Dieselweg 25, NL-3752 LB Bunschoten</td>
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<td>Oral use</td>
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<td>Member State</td>
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<td>Strength</td>
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<td>Fluvoxaminemaleaat 50 PCH, film coated tablets</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Oral use</td>
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<td>Fluvoxaminemaleaat Sandoz 50, coated tablets</td>
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<td>Sandoz B.V., Postbus 216, NL-1380 AE Weesp</td>
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<td>Fevarin 50, tablets</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Fluvoxaminemaleaat 25 mg, tablets</td>
<td>25 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Synthon B.V., Postbus 7071, NL-6503 GN Nijmegen</td>
<td>Fluvoxaminemaleaat 50 mg, tablets</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>100 mg</td>
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<td>Oral use</td>
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<td>Solvay Pharmaceuticals B.V., C.J. Van Houtenlaan 36, 1381 CP Weesp, NL</td>
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<td>Oral use</td>
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<td>Poland</td>
<td>Solvay Pharmaceuticals B.V., C.J. Van Houtenlaan 36, 1381 CP Weesp, NL</td>
<td>Fevarin</td>
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<td>Coated tablet</td>
<td>Oral use</td>
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<td>Portugal</td>
<td>Ciclum Farma Unipessoal Lda., Rua Alfredo da Silva nº 16, 2610-016 Amadora, Portugal</td>
<td>Fluvoxamina Ciclum 100 mg, comprimidos</td>
<td>100 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Portugal</td>
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<td>Fluvoxamina Sandoz 100 mg Comprimidos/Revestidos por Película</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Portugal</td>
<td>Sandoz GmbH, Biochemiestrasse, 10 A-6250 Kundl Austria</td>
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<td>50 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Portugal</td>
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<td>50 mg</td>
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<td>Portugal</td>
<td>Solvay Farma, Lda., Avenida Marechal Gomes da Costa, 33 1800-255 Lisboa Portugal</td>
<td>Dumyrox</td>
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<td>Oral use</td>
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<td>Slovak Republic</td>
<td>Solvay Pharmaceuticals B.V., CJ van Houtenlaan 36, NL - 1381 CP Weep</td>
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<td>Oral use</td>
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<td>Slovak Republic</td>
<td>Solvay Pharmaceuticals B.V., CJ van Houtenlaan 36, NL - 1381 CP Weep</td>
<td>FEVARIN 100</td>
<td>100mg</td>
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<td>Oral use</td>
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<td>Spain</td>
<td>SANDOZ FARMACEUTICA, S.A., Gran Via de les Corts Catalanes, 764 08013 Barcelona, Spain</td>
<td>FLUVOXAMINA SÁNDOZ</td>
<td>50 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>FLUVOXAMINA SÁNDOZ</td>
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<td>Oral use</td>
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<td>Spain</td>
<td>SOLVAY PHARMA, S.A., Avda. Diagonal, 507, 08029 Barcelona, Spain</td>
<td>DUMIROX</td>
<td>50 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Oral use</td>
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<td>Spain</td>
<td>TEVA GENERICOS ESPAÑOLA, S.L.C/ Guzman el Bueno 133, Edificio Britania 4ºIzq.Madrid, Spain</td>
<td>FLUVOXAMINA TEVA</td>
<td>100mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Spain</td>
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<td>FLUVOXAMINA TEVA</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Solvay Pharmaceuticals BV, CJ Van Houtenlaan 36 1381 CP Weesp Nederländerna (NLD)</td>
<td>Fevarin</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Strength</td>
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<td>Sweden</td>
<td>Stada Arzneimittel AG Stadastrasse 2-18 DE-61118 Bad Vilbel Tyskland (DEU)</td>
<td>Fluvosol</td>
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<td>Oral use</td>
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<td>United Kingdom</td>
<td>Approved Prescription Services Limited, Brampton Road, Hampden Park, Eastbourne, E Sussex BN22 9AG; UK</td>
<td>Fluvoxamine</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Fluvoxamine</td>
<td>100mg</td>
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<td>Oral use</td>
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<td>United Kingdom</td>
<td>CP Pharmaceuticals Limited, Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, UK</td>
<td>Fluvoxamine</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
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<td>Fluvoxamine</td>
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<td>United Kingdom</td>
<td>Solvay Healthcare Limited, Mansbridge Road, West End, Southampton SO18 3JD; UK</td>
<td>Faverin</td>
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<td>100mg</td>
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<td>United Kingdom</td>
<td>Stada Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany</td>
<td>Fluvomax</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>United Kingdom</td>
<td>Synthon BV, Microweg 22, Nijmegen, 6546 CM, Netherlands</td>
<td>Fluvoxamine</td>
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<td>Synthon BV, Microweg 22, Nijmegen, 6546 CM, Netherlands</td>
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<td>Oral use</td>
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<td>United Kingdom</td>
<td>Teva Pharmaceuticals Limited, Barclays House, 1 Gatehouse Way, Aylesbury, Bucks HP19 8DB; UK</td>
<td>Fluvoxamine</td>
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<td>Teva Pharmaceuticals Limited, Barclays House, 1 Gatehouse Way, Aylesbury, Bucks HP19 8DB; UK</td>
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<td>100mg</td>
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<td>United Kingdom</td>
<td>Tillomed Laboratories Limited; 3 Howard Road, Eaton Socon, St. Neots, Cambridgeshire PE19 3ET; UK</td>
<td>Fluvoxamine</td>
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<td>Oral use</td>
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<td>United Kingdom</td>
<td>Tillomed Laboratories Limited; 3 Howard Road, Eaton Socon, St. Neots, Cambridgeshire PE19 3ET; UK</td>
<td>Fluvoxamine</td>
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<td>Austria</td>
<td>Arcana Arzneimittel GmbH, Zimbagasse 5, 1147 Wien, Austria</td>
<td>Mianserin „Arcana“ 10mg-Filmtabletten</td>
<td>10mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Austria</td>
<td>Arcana Arzneimittel GmbH, Zimbagasse 5, 1147 Wien, Austria</td>
<td>Mianserin „Arcana“ 30mg-Filmtabletten</td>
<td>30mg</td>
<td>Film-coated tablet</td>
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<td>Austria</td>
<td>Organon Ges.m.b.H., Siebenbrunnengasse 21, 1050 Wien, Austria</td>
<td>Tolvon 30mg-Filmtabletten</td>
<td>30mg</td>
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<td>Oral use</td>
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<tr>
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<td>Organon Ges.m.b.H., Siebenbrunnengasse 21, 1050 Wien, Austria</td>
<td>Tolvon 60mg-Filmtabletten</td>
<td>60mg</td>
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<td>Ratiopharm Arzneimittel Vertriebs Ges.m.b.H., Albert Schweitzer-Gasse 3, 1140 Wien, Austria</td>
<td>Mianserin „ratiopharm“ 10mg-Filmtabletten</td>
<td>10mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Austria</td>
<td>Ratiopharm Arzneimittel Vertriebs Ges.m.b.H., Albert Schweitzer-Gasse 3, 1140 Wien, Austria</td>
<td>Mianserin „ratiopharm“ 30mg-Filmtabletten</td>
<td>30mg</td>
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<tr>
<td>Belgium</td>
<td>LAGEPHA S.A. Avenue Mercator 1 1300 Wavre, Belgium</td>
<td>Mianserine Lagepha</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>LAGEPHA S.A. Avenue Mercator 1 1300 Wavre, Belgium</td>
<td>Mianserin Lagepha</td>
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<td>Belgium</td>
<td>ORGANON EUROPE N.V. Kloosterstraat 6 5349 AB Oss, The Netherlands</td>
<td>Lerivon</td>
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<td>Oral use</td>
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<td>ORGANON EUROPE N.V. Kloosterstraat 6 5349 AB Oss, The Netherlands</td>
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<td>REMEDICA LTD, AHARNON STR, P.O.BOX 51706, INDUSTRIAL ESTATE 3508 LEMESOS, CYPRUS</td>
<td>Mianserin</td>
<td>10 mg</td>
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<td>Mianserin</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>MIANSERIN</td>
<td>60 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Czech Republic</td>
<td>GENERICS UK LIMITED, CLOSE POTTERS BAR, HERTS, Albany Gate, Darkes Lane, EN6 1AG Potters bar, Herefordshire, UK</td>
<td>MIANSERIN 10 MG GENERICS</td>
<td>10 mg</td>
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<td>Oral use</td>
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<td>GENERICS UK LIMITED, CLOSE POTTERS BAR, HERTS, Albany Gate, Darkes Lane, EN6 1AG Potters bar, Herefordshire, UK</td>
<td>MIANSERIN 60 MG GENERICS</td>
<td>60 mg</td>
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<td>Oral use</td>
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<td>Czech Republic</td>
<td>N.V.ORGANON, OSS, PO Box 20, 5340 BH Oss, Netherlands</td>
<td>LERIVON 10MG</td>
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<td>Oral use</td>
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<td>N.V.ORGANON, OSS, PO Box 20, 5340 BH Oss, Netherlands</td>
<td>LERIVON 30MG</td>
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<td>Oral use</td>
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<td>N.V.ORGANON, OSS, PO Box 20, 5340 BH Oss, Netherlands</td>
<td>LERIVON 60MG</td>
<td>60 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Czech Republic</td>
<td>RATIOPHARM GMBH, ULM, Graf-Arco-Strasse 3, 890 79 Ulm, Germany</td>
<td>MIABENE 10 MG</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>MIABENE 30 MG</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Durascan Medical Products A/S, C. F. Tietgen Boulevard 40, DK-5220 Odense SØ, Denmark</td>
<td>Tolmin</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
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<td>Tolmin</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Durascan Medical Products A/S, C. F. Tietgen Boulevard 40, DK-5220 Odense SØ, Denmark</td>
<td>Tolmin</td>
<td>60 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Gerard Laboratories, 35 Balcloyle Industrial Estate, Dublin, Ireland</td>
<td>Mianserin &quot;NM&quot;</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Gerard Laboratories, 35 Balcloyle Industrial Estate, Dublin, Ireland</td>
<td>Mianserin &quot;NM&quot;</td>
<td>30 mg</td>
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<td>Denmark</td>
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<td>Tolvon</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Tolvon</td>
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<td>Tolvon</td>
<td>60 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>N.V.Organon, Kloosterstraat 6, P.O.BOX 20, 5340, the Netherlands</td>
<td>Tolvon</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Miaxan</td>
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<td>Oral use</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Miaxan</td>
<td>60 mg</td>
<td>Film-coated tablet</td>
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<td>France</td>
<td>Arrow generiques 26 avenue Tony Garnier 69007 Lyon - France</td>
<td>MIANSERINE ARROW</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>France</td>
<td>Arrow generiques 26 avenue Tony Garnier 69007 Lyon - France</td>
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<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Oral use</td>
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<td>Lantanon</td>
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<td>HEXAL AG, Industrie Strasse 25, D-83607 Holzkirchen, Germany</td>
<td>Mianeurin</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Generics UK Ltd, Station Close, Potters Bar, EN6 1TL, Herts, UK</td>
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<td>Oral use</td>
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<td>Generics UK Ltd, Station Close, Potters Bar, EN6 1TL, Herts, UK</td>
<td>Mianserin BP</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Norton Healthcare Ltd., Ivax Quays, Albert Basin, Royal Docks London E16 2QJ United Kingdom</td>
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<td>Genfarma B.V., Postbus 2062, NL-1500 GB Zaandam</td>
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<td>Oral use</td>
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<td>Mianserin HCl 10 mg Katwijk, tablets</td>
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<td>Katwijk Farma B.V., Postbus 408, NL-2300 AK Leiden</td>
<td>Mianserin HCl 30 mg Katwijk, tablets</td>
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<td>Oral use</td>
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<td>Strength</td>
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<td>Tolvon, tablets 10 mg</td>
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<td>Tolvon, tablets 3 mg</td>
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<td>Oral use</td>
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<td>Tolvon 60 mg, tablets</td>
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<td>Mianserine HCl 10 PCH, tablets</td>
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<td>Merck NM AB, Box 25033, SE-104 35 Stockholm, Sweden</td>
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<td>Oral use</td>
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<td>Norway</td>
<td>Merck NM AB, Box 25033, SE-104 35 Stockholm, Sweden</td>
<td>Mianserin Merck NM</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
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<td>Merck NM AB, Box 25033, SE-104 35 Stockholm, Sweden</td>
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<td>Film-coated tablet</td>
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<td>10 mg</td>
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<td>Oral use</td>
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<td>Mianserin</td>
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<td>Coated tablet</td>
<td>Oral use</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Organon Portuguesa - Produtos Químicos e Farmacêuticos, Lda., Avenida Conde de Valbom, n.º 30 - 2º 1069-037 Lisboa Portugal</td>
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<td>30 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Oral use</td>
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<td>LERIVON</td>
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<td>Oral use</td>
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<td>LERIVON</td>
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<td>Oral use</td>
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<td>SALUS Ljubljana, d.d., Mašera Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia</td>
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<td>30 mg</td>
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<td>Oral use</td>
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<td>10 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>ORGANON ESPAÑOLA  Ctra. Hospitalet, 147-149 Cityparc Ronda de Dalt, Edificio Amsterdam 08940, Spain</td>
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<td>Oral use</td>
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<td>Mianserin Merck NM</td>
<td>10 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Oral use</td>
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<td>60 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Oral use</td>
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<td>30 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<tr>
<td>United Kingdom</td>
<td>Generics (UK) Limited; Albany Gate; Darkes Lane; Potters Bar, Herts EN6 1AG; UK</td>
<td>Mianserin</td>
<td>10mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>United Kingdom</td>
<td>Generics (UK) Limited; Albany Gate; Darkes Lane; Potters Bar, Herts EN6 1AG; UK</td>
<td>Mianserin</td>
<td>20mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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**MILNACIPRAN containing medicinal products with Marketing Authorisation in the European Union**

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<th>Invented Name</th>
<th>Strength</th>
<th>Pharmaceutical form</th>
<th>Route of administration</th>
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<td>Austria</td>
<td>Pierre Fabre Medicament, 45, Place Abel Gance, 92100 Boulogne, France</td>
<td>Dalcipran 25mg-Kapseln</td>
<td>25mg</td>
<td>Capsule, hard</td>
<td>Oral use</td>
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<td>Pierre Fabre Médicament Portugal, Lda., Rua Rodrigo da Fonseca, n.º 178 - 2º Esq. 1099-067 Lisboa Portugal</td>
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**MIRTAZAPINE containing medicinal products with Marketing Authorisation in the European Union**

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<th>Strength</th>
<th>Pharmaceutical form</th>
<th>Route of administration</th>
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<td>Mirtazapin “Alternova” 15mg-Filmttabletten</td>
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<td>Belgium</td>
<td>MERCK N.V. Brusselsesteenweg 288 3090 OVERIJSE, Belgium</td>
<td>Merck Mirtazapine</td>
<td>15 mg</td>
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<td>Oral use</td>
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<td>Belgium</td>
<td>MERCK N.V. Brusselsesteenweg 288 3090 OVERIJSE, Belgium</td>
<td>Merck Mirtazapine</td>
<td>30 mg</td>
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<td>Belgium</td>
<td>MERCK N.V. Brusselsesteenweg 288 3090 OVERIJSE, Belgium</td>
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<td>ORGANON BELGIE Terhulpsesteenweg 166 1070 BRUSSEL, Belgium</td>
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<td>15 mg/ml</td>
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<td>Belgium</td>
<td>ORGANON EUROPE B.V. Kloosterstraat 6 5349 AB OSS The Netherlands</td>
<td>Remergon</td>
<td>15 mg</td>
<td>Tablet</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>15 mg</td>
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<td>Oral use</td>
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<td>Belgium</td>
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<td>Remergon soltab</td>
<td>30 mg</td>
<td>Orodispersible tablet</td>
<td>Oral use</td>
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<td>ORGANON EUROPE B.V. Kloosterstraat 6 5349 AB OSS The Netherlands</td>
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<td>RATIOPHARM S.A. Rue St, Lambert 141 1200 BRUXELLES, Belgium</td>
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<td>Belgium</td>
<td>SANDOZ N.V. Medialaan 40 1800 VILVOORDE, Belgium</td>
<td>Mirtazapine Sandoz</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Belgium</td>
<td>SANDOZ N.V. Medialaan 40 1800 VILVOORDE, Belgium</td>
<td>Mirtazapine Sandoz</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Invented Name</td>
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<td>Route of administration</td>
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<td>N.V.ORGANON, OSS PO Box 20,5340 BH Oss, Netherlands</td>
<td>Remeron Soltab 15mg</td>
<td>15 mg</td>
<td>Orodispensible tablet</td>
<td>Oral use</td>
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<td>Czech Republic</td>
<td>N.V.ORGANON, OSS PO Box 20,5340 BH Oss, Netherlands</td>
<td>Remeron Soltab 30mg</td>
<td>30 mg</td>
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<td>Czech Republic</td>
<td>N.V.ORGANON, OSS PO Box 20,5340 BH Oss, Netherlands</td>
<td>Remeron Soltab 45mg</td>
<td>45 mg</td>
<td>Orodispensible tablet</td>
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<td>Remeron 15 mg</td>
<td>15 mg</td>
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<td>Oral use</td>
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<td>Czech Republic</td>
<td>N.V.ORGANON, OSS PO Box 20,5340 BH Oss, Netherlands</td>
<td>Remeron 30 mg</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Remeron 45 mg</td>
<td>45 mg</td>
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<td>ZENTIVA A.S., 102 37 PRAHA U Kabelovny 130, Dolní Měcholupy, Czech Republic</td>
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<td>15 mg</td>
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<td>Member State</td>
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<td>Strength</td>
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<td>Route of administration</td>
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<td>30 mg</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Alternova A/S, Industriparken 25, DK-2750 Ballerup, Denmark</td>
<td>Mirtazapin &quot;Alternova&quot;</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Alternova A/S, Industriparken 25, DK-2750 Ballerup, Denmark</td>
<td>Mirtazapin &quot;Alternova&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Alternova A/S, Industriparken 25, DK-2750 Ballerup, Denmark</td>
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<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Arrow Generics Limited, Unit 2, Eastman Way, SG14SZ Hertfordshire, GB</td>
<td>Mirtazapin &quot;Arrow&quot;</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Arrow Generics Limited, Unit 2, Eastman Way, SG14SZ Hertfordshire, GB</td>
<td>Mirtazapin &quot;Arrow&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
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<td>Mirtazapin &quot;Arrow&quot;</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Combino Pharm S.L., C/Fructuos Gelabert 6-8, ES-08970 Sant Joan, Despi, Barc, Spain</td>
<td>Mirtazapin &quot;Combino Pharm&quot;</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Combino Pharm S.L., C/Fructuos Gelabert 6-8, ES-08970 Sant Joan, Despi, Barc, Spain</td>
<td>Mirtazapin &quot;Combino Pharm&quot;</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Combino Pharm S.L., C/Fructuos Gelabert 6-8, ES-08970 Sant Joan, Despi, Barc, Spain</td>
<td>Mirtazapin &quot;Combino Pharm&quot;</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Durascan Medical Products A/S, C. F. Tietgens Boulevard 40, DK-5220 Odense SØ, Denmark</td>
<td>Arintapin</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Durascan Medical Products A/S, C. F. Tietgens Boulevard 40, DK-5220 Odense SØ, Denmark</td>
<td>Arintapin</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Durascan Medical Products A/S, C. F. Tietgens Boulevard 40, DK-5220 Odense SØ, Denmark</td>
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<td>Film-coated tablet</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Mirtazapin &quot;HEXAL&quot;</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Mirtazapin &quot;HEXAL&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Mirtazapin &quot;HEXAL&quot;</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Imi Pharma AS, Literbuen 9, DK-2740 Skovlunde, Denmark</td>
<td>Remeron</td>
<td>15 mg/ml</td>
<td>Oral soulution</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Lichtenstein Pharmazeutica GmbH, Industriestrasse 10, D-56218 Mulheim-Karlich, Germany</td>
<td>Mirtazapin &quot;Lichtenstein&quot;</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Lichtenstein Pharmazeutica GmbH, Industriestrasse 10, D-56218 Mulheim-Karlich, Germany</td>
<td>Mirtazapin &quot;Lichtenstein&quot;</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Lichtenstein Pharmazeutica GmbH, Industriestrasse 10, D-56218 Mulheim-Karlich, Germany</td>
<td>Mirtazapin &quot;Lichtenstein&quot;</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>Denmark</td>
<td>N.V. Organon, P.O. Box 20, Oss, Netherland</td>
<td>Remeron Smelt</td>
<td>15 mg</td>
<td>Oral lyophilisate</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>N.V. Organon, P.O. Box 20, Oss, Netherland</td>
<td>Remeron Smelt</td>
<td>30 mg</td>
<td>Oral lyophilisate</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>N.V. Organon, P.O. Box 20, Oss, Netherland</td>
<td>Remeron Smelt</td>
<td>45 mg</td>
<td>Oral lyophilisate</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Neuraxpharm Arzneimittel GmbH, Elisabeth-Selbert-Strasse 23, D-40764 Langenfeld, Germany</td>
<td>Mirtazapin &quot;Neuraxpharm&quot;</td>
<td>15 mg</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Neuraxpharm Arzneimittel GmbH, Elisabeth-Selbert-Strasse 23, D-40764 Langenfeld, Germany</td>
<td>Mirtazapin &quot;Neuraxpharm&quot;</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Neuraxpharm Arzneimittel GmbH, Elisabeth-Selbert-Strasse 23, D-40764 Langenfeld, Germany</td>
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<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Mirtazapin &quot;Ratiopharm&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
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<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>Mirtazapin &quot;Sandoz&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>Mirtazapin &quot;Sandoz&quot;</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Stada Arzneimittel AG, Staclastrasse 2-18, D-61118 Bad Vibel, Germany</td>
<td>Combar</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Stada Arzneimittel AG, Staclastrasse 2-18, D-61118 Bad Vibel, Germany</td>
<td>Combar</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Stada Arzneimittel AG, Staclastrasse 2-18, D-61118 Bad Vibel, Germany</td>
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<td>Stada Arzneimittel AG, Staclastrasse 2-18, D-61118 Bad Vibel, Germany</td>
<td>Zicomber</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Zicomber</td>
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<td>Oral use</td>
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<td>Zicomber</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Mirtalich</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Denmark</td>
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<td>Mirtalich</td>
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<td>Film-coated tablet</td>
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<td>Estonia</td>
<td>N.V. ORGANON Kloosterstraat 6P.O.Box 205340 BH OssHolland</td>
<td>REMERON SOLTAB</td>
<td>15mg</td>
<td>Orodispersible tablet</td>
<td>Oral use</td>
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<td>Estonia</td>
<td>N.V. ORGANON Kloosterstraat 6P.O.Box 205340 BH OssHolland</td>
<td>REMERON SOLTAB</td>
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<td>Oral use</td>
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<td>Tablet</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Actavis Nordic A/S, Hammervej 7, HØRSHOLM 2970, Denmark</td>
<td>Mirtazapin Actavis</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Finland</td>
<td>Actavis Nordic A/S, Hammervej 7, HØRSHOLM 2970, Denmark</td>
<td>Mirtazapin Actavis</td>
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<td>Finland</td>
<td>Actavis Nordic A/S, Hammervej 7, HØRSHOLM 2970, Denmark</td>
<td>Mirtazapin Actavis</td>
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<td>Mirtaril</td>
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<td>Mirtazapin Lannacher</td>
<td>15 mg</td>
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<td>Remeron</td>
<td>15 mg</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>15 mg</td>
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<td>Oral use</td>
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<td>Orodispensible tablet</td>
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<td>ORGANON 10 Rue Godefroy Immeuble Optima 92821 Puteaux cedex - France</td>
<td>NORSET</td>
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<td>MIZAPIN 15 mg filmtabletta</td>
<td>15mg</td>
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<td>MIZAPIN 30 mg filmtabletta</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Actavis hf., Reykjavikurvegur 76-78, 220 Hafnarfjörður, Iceland</td>
<td>Miron</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Iceland</td>
<td>Generics UK Ltd. 12 Station Close Potters Bar, Herts, England</td>
<td>Mirtazapin NM Pharma</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Iceland</td>
<td>NV. Organon, PO Box 20 5340 HB Oss, Holland</td>
<td>Remeron</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>NV. Organon, PO Box 20 5340 HB Oss, Holland</td>
<td>Remeron</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>NV. Organon, PO Box 20 5340 HB Oss, Holland</td>
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<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Strength</td>
<td>Pharmaceutical form</td>
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<td>15 mg</td>
<td>Orodispensible tablet</td>
<td>Oral use</td>
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<td>Remeron Smelt</td>
<td>30 mg</td>
<td>Orodispensible tablet</td>
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<td>Orodispensible tablet</td>
<td>Oral use</td>
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<td>Ireland</td>
<td>McDermott Laboratories Ltd t/a Gerard Laboratories, 35 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland</td>
<td>Zistap</td>
<td>30 mg</td>
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<td>Zismirt</td>
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<td>Rowex Ltd, Bantry, Co. Cork, Ireland</td>
<td>Mirap</td>
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<td>Oral use</td>
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<td>Member State</td>
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<td>Strength</td>
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<td>Ireland</td>
<td>Organon (Ireland) Limited, PO Box 2857, Drynam Road, Swords, Co. Dublin, Ireland</td>
<td>Zispin</td>
<td>15 mg/ml</td>
<td>Oral solution</td>
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<td>Ireland</td>
<td>Organon (Ireland) Limited, PO Box 2857, Drynam Road, Swords, Co. Dublin, Ireland</td>
<td>Zispin</td>
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<td>Ireland</td>
<td>Organon (Ireland) Limited, PO Box 2857, Drynam Road, Swords, Co. Dublin, Ireland</td>
<td>Zispin</td>
<td>40 mg/ml</td>
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<td>Ireland</td>
<td>Organon Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 0FL, UK</td>
<td>Zispin</td>
<td>15 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Zispin</td>
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<td>Zispin</td>
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<tr>
<td>Italy</td>
<td>Alfred E. Tiefenbacher (GmbH &amp; Co. KG) Van-der-Smissen-Str. 1 22767 Hamburg - Germany</td>
<td>Arintapina</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Italy</td>
<td>Alfred E. Tiefenbacher (GmbH &amp; Co. KG) Van-der-Smissen-Str. 1 22767 Hamburg - Germany</td>
<td>Arintapina</td>
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<td>Film-coated tablet</td>
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<td>Arintapina</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Italy</td>
<td>EG S.p.A. Via Domenico Scarlatti, 31 20124 Milano Italy</td>
<td>Mirtazapina EG</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Strength</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Italy</td>
<td>KRKA Pharma Dublin Limited 1Stokes Places, St. Stephens Green, Dublin 2 Ireland</td>
<td>Mirtazapina KRKA</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
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<td>Italy</td>
<td>Merck Generics Italia S.p.A. Via Aquileia, 35 20092 Cinisello Balsamo - Milano Italy</td>
<td>Mirtazapina Merck Generics</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Mirtazapina Merck Generics</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Italy</td>
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<td>Remeron</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Remeron</td>
<td>15 mg</td>
<td>Orodispensible tablets</td>
<td>Oral use</td>
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<td>Remeron</td>
<td>15 mg/ml</td>
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<td>Remeron</td>
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<td>Oral use</td>
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<td>Orodispensible tablets</td>
<td>Oral use</td>
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<td>N. V. Organon Kloosterstraat 6 5949 AB- OSS The Netherlands</td>
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<td>45 mg</td>
<td>Coated tablets</td>
<td>Oral use</td>
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<td>Remeron</td>
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<td>Orodispensible tablets</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Strength</td>
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<td>N. V. Organon Kloosterstraat 6 5949 AB- OSS The Netherlands</td>
<td>Remeron</td>
<td>3mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Intravenous use</td>
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<td>N. V. Organon Kloosterstraat 6 5949 AB- OSS The Netherlands</td>
<td>Remeron</td>
<td>3mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Intravenous use</td>
</tr>
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<td>N. V. Organon Kloosterstraat 6 5949 AB- OSS The Netherlands</td>
<td>Remeron</td>
<td>3mg/ml</td>
<td>Concentrate for solution for infusion</td>
<td>Intravenous use</td>
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<td>Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Germania</td>
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<td>30 mg</td>
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<td>Mirzaten</td>
<td>30 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Mirzaten</td>
<td>45 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Latvia</td>
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<td>Remeron</td>
<td>30 mg</td>
<td>Orodispersible tablet</td>
<td>Oral use</td>
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<td>Latvia</td>
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<td>Remeron SolTab</td>
<td>15 mg</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Dispersible tablet</td>
<td>oral use</td>
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<td>Remergon</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Remergon</td>
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<td>ORGANON EUROPE B.V. Kloosterstraat 6 5349 AB OSS The Netherlands</td>
<td>Remergon</td>
<td>3mg/ml</td>
<td>Infusion</td>
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<td>15 mg</td>
<td>Dispersible tablets</td>
<td>Oral use</td>
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<td>Luxembourg</td>
<td>ORGANON EUROPE B.V. Kloosterstraat 6 5349 AB OSS The Netherlands</td>
<td>Remergon</td>
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<td>Dispersible tablets</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>45 mg</td>
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<td>Luxembourg</td>
<td>Ratiopharm GmbH, Postfach 3380, D-89070 Ulm, Germany</td>
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<td>15 mg</td>
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</tr>
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<td>Netherlands</td>
<td>Alpharma B.V. Postbus 313 3740 AH Baarn, The Netherlands</td>
<td>Mirtazapine Dumex 15 mg, filmomhulde tabletten</td>
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<td>Mirtazapine CF 15 mg, filmomhulde tabletten</td>
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<td>Netherlands</td>
<td>Genfarma B.V. Postbus 2062 1500 GB Zaandam, The Netherlands</td>
<td>Mirtazapine Gf 15 mg, filmomhulde tabletten</td>
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<td>Katwijk Farma B.V. Postbus 408 2300 AK Leiden, The Netherlands</td>
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<td>Route of administration</td>
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<td>Netherlands</td>
<td>Merck Generics BV, Dieselweg 25, NL-3752 LB Bunschoten, The Netherlands</td>
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<td>N.V. Organon t.a.v. Mw.drs.S.A. Hendriksen KR 4418 Postbus 20 5340 BH Oss, The Netherlands</td>
<td>Mirtazapine 15 mg orodispergeerbaar tabletten, orodispergeerbaar tabletten</td>
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<td>Oral use</td>
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<td>N.V. Organon, Postbus 20, NL-5340 BH Oss</td>
<td>Remeron 30 mg, tablets</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Netherlands</td>
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<td>Remeron SolTab 45 mg, orodispersible tablet</td>
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<td>Mirtazapine 15 PCH, filmcoated tablets 15 mg</td>
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<td>Mirtazapine Sandoz 15, filmomhulde tabletten 15 mg</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Sandoz B.V. Postbus 216 1380 AE Weesp, The Netherlands</td>
<td>Mirtazapine Sandoz 30, filmomhulde tabletten 30 mg</td>
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<td>Film-coated tablet</td>
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<td>Norway</td>
<td>Alfred E. Tiefenbacher (GmbH &amp; Co. KG), Van-der Smissen-Str. 1, DE-22767 Hamburg, Germany</td>
<td>Mirtachem</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Mirtazapin Alpharma</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Mirtazapin Alpharma</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Norway</td>
<td>Alternova AS, Holmengata 24, NO-1394 Nesbru, Norway</td>
<td>Mirtazapin Alternova</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Alternova AS, Holmengata 24, NO-1394 Nesbru, Norway</td>
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<td>Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire SGI 4SZ, United Kingdom</td>
<td>Mirtazapin Arrow</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Strength</td>
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<td>30 mg</td>
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<td>Oral use</td>
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<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Mirtazapin Hexal</td>
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<td>Merck NM AB, Box 25033, SE-104 35 Stockholm, Sweden</td>
<td>Mirtazapin Merck NM</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Norway</td>
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<td>Remeron</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
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<td>45 mg</td>
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<td>Oral use</td>
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<td>Orodispersible tablet</td>
<td>Oral use</td>
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<td>Miralix</td>
<td>30 mg</td>
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<td>Oral use</td>
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<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, DE-89079 Ulm, Germany</td>
<td>Miralix</td>
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<td>N.V. Organon, P.O.Box 20, NL - 5340 BH OSS</td>
<td>REMERON 15mg/ml</td>
<td>15mg/ml</td>
<td>Oral solution</td>
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<tr>
<td>Slovenia</td>
<td>KRKA, tovarna zdravil, d.d., Novo mesto, Šmarješka cesta 6, SI-8501 Novo mesto, Slovenia</td>
<td>MIRZATEN</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Slovenia</td>
<td>KRKA, tovarna zdravil, d.d., Novo mesto, Šmarješka cesta 6, SI-8501 Novo mesto, Slovenia</td>
<td>MIRZATEN</td>
<td>45 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Slovenia</td>
<td>SALUS Ljubljana, d.d., Mašera Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia</td>
<td>REMERON</td>
<td>30 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>MIRTAZAPINA BAYVIT</td>
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<td>BEXAL FARMACEUTICA, S.A Ventura Rodriguez, 7 - 5ª planta, 28008 Madrid, Spain</td>
<td>MIRTAZAPINA BEXAL</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>MIRTAZAPINA DAVUR</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>MIRTAZAPINA DAVUR</td>
<td>30 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>MIRTAZAPINA MERCK</td>
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<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
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<td>45 mg</td>
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<td>REXER</td>
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<td>ORGANON ESPAÑOLA, S.A., Ctra. Hospitalet, 147-149 Cityparc Ronda de Dalt, Edificio Ámsterdam, 08940 Cornella de Llobregat, Spain</td>
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<td>REXER</td>
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<td>Oral use</td>
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<td>Spain</td>
<td>PENSA, S.A., Avda. Mare de Déu de Montserrat, 215, 08041 Barcelona, Spain</td>
<td>VASTAT FLAS</td>
<td>15 mg</td>
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<td>Oral use</td>
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<td>MIRTAZAPINA RATIO MED</td>
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<td>Strength</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>MIRTAZAPINA SANDOZ</td>
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<td>Sweden</td>
<td>Alfred E Tiefenbacher (Gmbh &amp; Co. KG) Van-der-Smissen Strasse 1 DE-22767 Hamburg Tyskland (DEU)</td>
<td>Mirtachem</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Sweden</td>
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<td>Mirtachem</td>
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<td>Sweden</td>
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<td>Mirtazapin Alpharma</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>45 mg</td>
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<td>Oral use</td>
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<tr>
<td>Sweden</td>
<td>Arrow Generics Ltd Unit 2 Eastman Way Stevenage Herts SGI 4SZ Storbritannien och Nordirland (GBR)</td>
<td>Mirtazapin Arrow</td>
<td>15 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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## PAROXETINE containing medicinal products with Marketing Authorisation in the European Union

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<th>Invented Name</th>
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<th>Pharmaceutical form</th>
<th>Route of administration</th>
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<td>1A Pharma GmbH, Degengasse 70, 1160 Wien, Austria</td>
<td>Paroxetin “1A Pharma” 20mg-Filmtabletten</td>
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<td>Route of administration</td>
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<tr>
<td>Belgium</td>
<td>MERCK N.V. Brusselsesteenweg 288, 3090 OVERIJSE, Belgium</td>
<td>MERCK PAROXETINE</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Belgium</td>
<td>RATIOPHARM S.A. Rue St, Lambert 141 1200 BRUXELLES, Belgium</td>
<td>PAROXETINE RATIOPHARM</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Belgium</td>
<td>RATIOPHARM S.A. Rue St, Lambert 141 1200 BRUXELLES, Belgium</td>
<td>PAROXETINE RATIOPHARM</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Belgium</td>
<td>SANDOZ N.V. Medialaan 40 1800 VILVOORDE, Belgium</td>
<td>PAROXETINE SANDOZ</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Belgium</td>
<td>TEVA PHARMA BELGIUM Laarstraat 16 2610 WILRIJK, Belgium</td>
<td>PAROXETINE TEVA</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Belgium</td>
<td>TOPGEN N.V. Demunterlaan 1 1090 BRUSSEL, Belgium</td>
<td>PAROXETINE TOPGEN</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Cyprus</td>
<td>MEDOCHEMIE LTD, P.O.BOX 51409, 3505 LEMESOS, CYPRUS</td>
<td>ARKETIS</td>
<td>30 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<tr>
<td>Cyprus</td>
<td>C A PAPAELLINA &amp; CO LTD, P.O.BOX 24018, LAXIA 1700 LEFKOSIA, CYPRUS</td>
<td>SEROXAT</td>
<td>30 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Cyprus</td>
<td>MEDOCHEMIE LTD, P.O.BOX 51409, 3505 LEMESOS, CYPRUS</td>
<td>ARKETIS</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Cyprus</td>
<td>SMITHKLINE BEECHAM PLC 980 GREAT WEST ROAD BRENTFORD MIDDLESEX TW8 9GS UK</td>
<td>SEROXAT</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>APOTEX EUROPE LTD., READING, Rowan House 41 London Street, Reading, Berkshire, RG1 4PS, UK</td>
<td>APO-PAROX</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>CHEMICAL WORKS OF GEDEON RICHTER LTD., 1103 BUDAPEST, Győmrői út 19-21, HUNGARY</td>
<td>REMOOD 20 MG</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>CHEMICAL WORKS OF GEDEON RICHTER LTD., 1103 BUDAPEST, Győmrői út 19-21, HUNGARY</td>
<td>REMOOD 30 MG</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>HEXAL A/S, 2650 HVIDOVRE, Kanalholmen 8-12, DENMARK</td>
<td>PAROLEX 20</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
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<td>Route of administration</td>
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<td>Czech Republic</td>
<td>HEXAL A/S, 2650 HVIDOVRE, Kanalholmen 8-12, DENMARK</td>
<td>PAROLEX 40</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Czech Republic</td>
<td>RATIOPHARM GMBH, ULM, Graf-Arco-Strasse 3, 890 79 Ulm, Germany</td>
<td>PAROXETIN-RATIOPHARM 20 MG</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>SMITHKLINE BEECHAM PHARMACEUTICALS, TW8 9EP Brentford, Middlesex, New Horizont Court, UK</td>
<td>SEROXAT 20 MG</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>SMITHKLINE BEECHAM PHARMACEUTICALS, TW8 9EP Brentford, Middlesex, New Horizont Court, UK</td>
<td>SEROXAT 30 MG</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>1A Farma A/S, Herstedøstervej 27-29, DK-2620 Albertslund, Denmark</td>
<td>Paroxetine &quot;1A Farma&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>1A Farma A/S, Herstedøstervej 27-29, DK-2620 Albertslund, Denmark</td>
<td>Paroxetine &quot;1A Farma&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK-2970 Hørsholm, Denmark</td>
<td>Paroxetine &quot;Actavis&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<tr>
<td>Denmark</td>
<td>Actavis Nordic A/S, Hammervej 7, DK-2970 Hørsholm, Denmark</td>
<td>Paroxetine &quot;Actavis&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Alpharma AS, Harbitzalleen 3, N-0212 Skoyen, Oslo, Norway</td>
<td>Paroxetine &quot;Alpharma&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Betapharm Arzneimittel GmbH, Steinerne Furt 78, D-86167 Augsburg, Germany</td>
<td>Roxac</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Betapharm Arzneimittel GmbH, Steinerne Furt 78, D-86167 Augsburg, Germany</td>
<td>Roxac</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Copyfarm A/S, Energivej 15, DK-5260 Odense S, Denmark</td>
<td>Paroxetine &quot;Copyfarm&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Copyfarm A/S, Energivej 15, DK-5260 Odense S, Denmark</td>
<td>Paroxetine &quot;Copyfarm&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Durascan Medical Products A/S, C. F. TietgensBoulevard 40, DK-5220 Odense SØ, Denmark</td>
<td>Serodur</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<tr>
<td>Denmark</td>
<td>Generics (UK) Ltd., Station Close, Potters Bar, UK-EN61TL Hertfordshire, GB</td>
<td>Paroxetine Generics&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Generics (UK) Ltd., Station Close, Potters Bar, UK-EN61TL Hertfordshire, GB</td>
<td>Pasero</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Genthon BV, Microweg 22, NL-6545 CM Nijmegen, Netherland</td>
<td>Paroxetine &quot;Genthon&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>GlaxoSmithKline Pharma A/S, Nykær 68, DK-2605 Brøndby, Denmark</td>
<td>Seroxat</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>GlaxoSmithKline Pharma A/S, Nykær 68, DK-2605 Brøndby, Denmark</td>
<td>Seroxat</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>GlaxoSmithKline Pharma A/S, Nykær 68, DK-2605 Brøndby, Denmark</td>
<td>Seroxat</td>
<td>2 mg/ml</td>
<td>Oral suspension</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre</td>
<td>Oxetine</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<tr>
<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Optipar</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Optipar</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Paroc</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Paroc</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Paroneurin</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Paroneurin</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Paroxetin &quot;HEXAL&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>HEXAL A/S, Kanalholmen 8-12, DK-2650 Hvidovre, Denmark</td>
<td>Paroxetin &quot;HEXAL&quot;</td>
<td>40 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Merck NM AB, Ynglingagatan 14, 11347, P.Box 22033, S-10435 Stockholm, Sweden</td>
<td>Paroxetin &quot;Merck NM&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Merck NM AB, Ynglingagatan 14, 11347, P.Box 22033, S-10435 Stockholm, Sweden</td>
<td>Paroxetin &quot;Merck NM&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>PharmaCoDane ApS, Marielundvej 46A, DK-2730 Herlev, Denmark</td>
<td>Paroxetin &quot;PCD&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Pharmascope Ltd, Medici House, Unit 107, Ashbourne Industrial Estate, CoMeath, Ireland</td>
<td>Meparox</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Pharmascope Ltd, Medici House, Unit 107, Ashbourne Industrial Estate, CoMeath, Ireland</td>
<td>Meparox</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Pharmascope Ltd, Medici House, Unit 107, Ashbourne Industrial Estate, CoMeath, Ireland</td>
<td>Paroscope</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Pharmascope Ltd, Medici House, Unit 107, Ashbourne Industrial Estate, CoMeath, Ireland</td>
<td>Paroscope</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graft-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Paroxegen</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Ratiopharm GmbH, Graft-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Paroxegen</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graft-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Paroxetin &quot;Ratiopharm&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Ratiopharm GmbH, Graft-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Pasorex</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Ratiopharm GmbH, Graft-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Sopax</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>Paroxetin &quot;Sandoz&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
<td>Marketing Authorisation Holder</td>
<td>Invented Name</td>
<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Denmark</td>
<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>Paroxetin &quot;Sandoz&quot;</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria</td>
<td>Paroxetin &quot;Sandoz&quot;</td>
<td>20 mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<tr>
<td>Denmark</td>
<td>Scand Pharm Generics AB, Ynglinagatan 14, S-11347 Stockholm, Sweden</td>
<td>Serorex</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
</tr>
<tr>
<td>Denmark</td>
<td>Scand Pharm Generics AB, Ynglinagatan 14, S-11347 Stockholm, Sweden</td>
<td>Serorex</td>
<td>30 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Scand Pharm Generics AB, Ynglinagatan 14, S-11347 Stockholm, Sweden</td>
<td>Seroxetabs</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Synthon BV, Microweg 22, NL-6545 CM, Nijmegen, Netherland</td>
<td>Euplix</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Synthon BV, Microweg 22, NL-6545 CM, Nijmegen, Netherland</td>
<td>Paroxetin &quot;Synthon&quot;</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Parsyn</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Synthon BV, Microweg 22, NL-6545 CM, Nijmegen, Netherland</td>
<td>Varoxetin</td>
<td>20 mg</td>
<td>Film-coated tablet</td>
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<tr>
<td>Estonia</td>
<td>Glaxo Group Ltd Berkeley Avenue, Greenford Middlesex TW8 9GS United Kingdom</td>
<td>PAROXAT</td>
<td>20mg</td>
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<tr>
<td>Estonia</td>
<td>Hexal AG Industriestrasse 25 83607 Holzkirchen Germany</td>
<td>PAROXETINHEXAL 20</td>
<td>20mg</td>
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<tr>
<td>Estonia</td>
<td>Hexal AG Industriestrasse 25 83607 Holzkirchen Germany</td>
<td>PAROXETINHEXAL 40</td>
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Elisabeth-Selbert-Str. 1  
D-40764 Langenfeld       | Paroxetin-ISIS 20 mg  
Filmtabletten              | 20 mg          | Film-coated tablet          | Oral use              |
| Germany      | AWD.pharma GmbH & Co. KG  
Leipziger Str. 7-13  
D-01097 Dresden              | Paroxetin AWD 20 mg  
Filmtabletten                | 20 mg          | Film-coated tablet          | Oral use              |
| Germany      | Basics GmbH  
Hennemelrather Weg 201  
D-51377 Leverkusen           | PAROXETIN BASICS  
20mg Filmtabletten           | 20 mg          | Film-coated tablet          | Oral use              |
| Germany      | Betapharm Arzneimittel GmbH  
Kobelweg 95  
D-86156 Augsburg             | Paroxetin beta 20 mg  
Filmtabletten                 | 20 mg          | Film-coated tablet          | Oral use              |
| Germany      | Betapharm Arzneimittel GmbH  
Kobelweg 95  
D-86156 Augsburg             | Paroxetin beta 40 mg  
Filmtabletten                 | 40 mg          | Film-coated tablet          | Oral use              |
| Germany      | Biomo pharma GmbH  
Josef-Dietzgen-Str. 3  
D-53773 Hennef               | paroxetin-biomo 20mg   | 20 mg          | Film-coated tablet          | Oral use              |
| Germany      | ct-Arzneimittel GmbH  
Lengeder Str. 42a  
D-13407 Berlin                | paroxetin von ct 20 mg  
Filmtabletten                | 20 mg          | Film-coated tablet          | Oral use              |
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<td>Actavis hf., Reykjavikurvegi 76-78, 220 Hafnarfjörður, Iceland</td>
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<td>Ireland</td>
<td>McDermott Laboratories Ltd t/a Gerard Laboratories, 35 Baldoyle Industrial Estate, Grange Road, Dublin 13 Ireland</td>
<td>Paxt</td>
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<td>McDermott Laboratories Ltd t/a Gerard Laboratories, 35 Baldoyle Industrial Estate, Grange Road, Dublin 13 Ireland</td>
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<td>Genthon B.V., Microweg 22, 6545 CM Nijmegen, The Netherlands</td>
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<td>Abbott S.p.A. Via Pontina km 52 04010 Campoverde - Latina Italy</td>
<td>Sereupin</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Oral solution</td>
<td>Oral use</td>
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<td>Daparox</td>
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<td>Italy</td>
<td>EG S.p.A. Via Domenico Scarlatti, 31 20124 Milano Italy</td>
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<td>Actavis hf, Reykjavikurvegur 78, 220, Hafnarfjordur, Iceland</td>
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<td>Alpharma B.V. Postbus 313 3740 AH Baarn, The Netherlands</td>
<td>Paroxetine Dumex O.F. 20 mg tabletten, filmomhulde tabletten</td>
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<td>Paroxetine CF 30 mg, filmomhulde tabletten</td>
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<td>Oral use</td>
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<td>Netherlands</td>
<td>Centrafarm Services B.V. Postbus 289 4870 AG Etten Leur, The Netherlands</td>
<td>Paroxetine CF 2 mg/ml, suspensie voor oraal gebruik</td>
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<td>Netherlands</td>
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<td>Paroxetine Gf 20 mg, omhulde tabletten</td>
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<td>Coated tablet</td>
<td>Oral use</td>
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<td>Netherlands</td>
<td>Genfarma B.V. Postbus 2062 1500 GB Zaandam, The Netherlands</td>
<td>Paroxetine Gf 2 mg/ml suspensie, suspensie voor oraal gebruik</td>
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<td>Film-coated tablet</td>
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<td>Seroxat Suspensie 2 mg/ml, suspensie voor oraal gebruik</td>
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<td>Paroxetine Tablet OF, filmomhulde tabletten 20 mg</td>
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<td>Film-coated tablet</td>
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<td>Oral use</td>
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<td>GlaxoSmithKline B.V. Postbus 780 3700 AT Zeist</td>
<td>Paroxetine GSK suspensie 2 mg/ml, suspensie voor oraal gebruik</td>
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<td>Oral solution</td>
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<td>Invented Name</td>
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<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Copyfarm AS, Energivej 15, DK 5260 Odense S, Denmark</td>
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<td>Durascan Medical Products AS, C. F. Tietgens Boulevard 40, DK-5220 Odense SØ, Denmark</td>
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<td>Merck NM AB, Box 25033, SE-104 35 Stockholm, Sweden</td>
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<td>Irex - Promoção e Comercialização de Produtos Farmacêuticos, Lda, Praça Duque de Saldanha n.º 1 - 4º E 1050-094 Lisboa Portugal</td>
<td>Paroxetina Irex 20 mg Comprimidos Revestidos</td>
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<td>toLife - Produtos Farmacêuticos, S.A., Estrada Consiglieri Pedroso nº 71, 5º D - Queluz de Baixo 2730-055 Barcarena Portugal</td>
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<td>Paroxetina Bexal 20 mg Comprimidos Revestidos por Película</td>
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<td>Laboratório Normal - Produtos Farmacêuticos, S.A., Rua do Centro Empresarial, Edifício 8 - Quinta da Beloura 2710-444 Sintra Portugal</td>
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<td>PAROXETINA HEXAL 20 mg</td>
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<td>PAROXETINA ACOST 20 MG COMPRIMIDOS RECUBIERTOS</td>
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<td>Paroxetine Davur</td>
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<td>PARATONINA</td>
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<td>FOURNIER, S.A., Centro Empresarial Euronova. Ronda de Poniente, 16, 2º A, Tres Cantos, 28760, Spain</td>
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<td>LABORATORIO STADA, S.L., Frederic Mompou, 5, Sant Just Desvern, 08960, Spain</td>
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<td>Paroxetina MERCK 20 mg comprimidos recubiertos</td>
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<td>PAROXETINA MUNDOGEN 20 mg comprimidos con cubierta pelicular</td>
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<td>NOVARTIS FARMACEUTICA, S.A., Gran Via de les Corts Catalanes, 764, Barcelona, 08013, Spain</td>
<td>FROSINOR 20 mg comprimidos con cubierta pelicular</td>
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<td>PAROXETINA SANDOZ 20 MG COMPRIMIDOS</td>
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<td>PAROXETINA TARBIS 20 MG COMPRIMIDOS RECUBIERTOS CON PELÍCULA</td>
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<td>Invented Name</td>
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<td>20 mg</td>
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<td>Actavis Nordic A/S Hammervej 7 DK-2970 Hörsholm Danmark (DNK)</td>
<td>Paroxetin Actavis</td>
<td>20 mg</td>
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<td>Alpharma AS, P.O. Box 158 Sköyen N-0212 Oslo Norge (NOR)</td>
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<td>Sweden</td>
<td>Apotex Europe Ltd Rowan House 41, London Street Reading, Berkshire RG1 4PS Storbritannien och Nordirland (GBR)</td>
<td>Paroxetin IVAX</td>
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<td>Oral use</td>
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<td>Sweden</td>
<td>AWD.pharma GmbH &amp; Co. KG Lepziger Strasse 7-13 D-01097 Dresden Tyskland (DEU)</td>
<td>Paroximed</td>
<td>20 mg</td>
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<td>Oral use</td>
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<td>DuraScan Medical Products A/S C.F.Tietgens Boulevard 40 DK-5220 Odense SØ Danmark (DNK)</td>
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<td>Oral use</td>
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<td>Gerard Laboratories 35/36 Baldoyle Industrial Estate Grange Road Dublin 13 Irland (IRL)</td>
<td>Paroxetin Scand Pharm</td>
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<td>Film-coated tablet</td>
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<td>Member State</td>
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**REBOXETINE containing medicinal products with Marketing Authorisation in the European Union**

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<td>Sertraline EG</td>
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**SERTRALINE containing medicinal products with Marketing Authorisation in the European Union**
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<td>Sertralin &quot;1A Farma&quot;</td>
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<td>Route of administration</td>
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<td>Oral use</td>
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<td>Laboratoires IREX, 22 Avenue Galilée, 92350 Le Plessis Robinson, France</td>
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<td>50 mg</td>
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<td>Oral use</td>
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<td>100 mg</td>
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<td>Oral use</td>
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<td>Zoloft</td>
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<td>Oral use</td>
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<td>Zoloft</td>
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<td>Oral use</td>
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<td>Denmark</td>
<td>Ranbaxy (UK) Limited, 95 Park Lane, Mayfair, UK-W1K7TE, London, GB</td>
<td>Sertralin &quot;Ranbaxy&quot;</td>
<td>50 mg</td>
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<td>Oral use</td>
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<td>Ranbaxy (UK) Limited, 95 Park Lane, Mayfair, UK-W1K7TE, London, GB</td>
<td>Sertralin &quot;Ranbaxy&quot;</td>
<td>100 mg</td>
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<td>Oral use</td>
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<td>Sertralin &quot;Ratiopharm&quot;</td>
<td>50 mg</td>
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<td>Oral use</td>
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<td>Ratiopharm GmbH, Grat-Arco-Strasse 3, D-89079 Ulm, Germany</td>
<td>Sertralin &quot;Ratiopharm&quot;</td>
<td>100 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Denmark</td>
<td>Stada Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vibel, Germany</td>
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<td>50 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>100 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Member State</td>
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<td>ASENTRA</td>
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<td>Tablet</td>
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<td>ASENTRA</td>
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<td>Tablet</td>
<td>Oral use</td>
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<td>Estonia</td>
<td>Pfizer H.C.P. Corporation Eesti, Pirita tee 20, 10127 TALLINN, Estonia</td>
<td>ZOLOFT</td>
<td>50mg</td>
<td>Tablet</td>
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<td>Hexal A/S, Kanalholmen 8-12, 2650 HVIDOVRE, Denmark</td>
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<td>50 mg</td>
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<td>Hexal A/S, Kanalholmen 8-12, 2650 HVIDOVRE, Denmark</td>
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<td>Oral use</td>
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<td>Member State</td>
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<td>Invented Name</td>
<td>Strength</td>
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<td>Zoloft</td>
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<td>Pfizer Oy, Tietokuja 4, 00330 HELSINKI, Finland</td>
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<td>Oral use</td>
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<td>BERAL 23 -25 Avenue du Docteur Lannelongue 75668 Paris cedex 14- France</td>
<td>SERTRALINE BERAL</td>
<td>100 mg</td>
<td>Capsule, hard</td>
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<td>BERAL 23 -25 Avenue du Docteur Lannelongue 75668 Paris cedex 14- France</td>
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<td>50 mg</td>
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<td>Oral use</td>
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<td>Lustral</td>
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<td>100mg</td>
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<td>Serlan</td>
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<td>Serlan</td>
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<td>Oral use</td>
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<td>Italy</td>
<td>Alfred E. Tiefenbacher (GmbH &amp; Co. KG) Van-der-Smissen-Str. 1 22767 Hamburg - Germany</td>
<td>Sertralina Tiefenbacher</td>
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<td>Oral use</td>
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<td>Alfred E. Tiefenbacher (GmbH &amp; Co. KG) Van-der-Smissen-Str. 1 22767 Hamburg - Germany</td>
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<td>Oral use</td>
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<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Bioindustria Farmaceutici S.r.l. Via Valbondione 113, 00188 Roma, Italy</td>
<td>Zoloft</td>
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<td>Ranbaxy (UK) Ltd, 6rd floor,C.P. House, 97-107 Uxbridge Road, Ealing, London, W5 5TL UNITED KINGDOM</td>
<td>Serlift</td>
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<td>Pfizer AS, P.O.Box 3, NO-1324 Lysaker, Norway</td>
<td>Zoloft</td>
<td>25 mg</td>
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<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Norway</td>
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<td>Sertralin Ranbaxy</td>
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<td>Oral use</td>
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<td>Stada Arzneimittel AG, Stada Strasse 2-18, DE-61118 Bad Vilbel, Germany</td>
<td>Sertralin Stada</td>
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<td>Strength</td>
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<td>Route of administration</td>
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<td>Sertrabeck 100 mg</td>
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<td>Oral use</td>
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<td>Jelfa S.A. Przedsiębiorstwo Farmaceutyczne, Wincentego Pola 21 58-500 Jelenia Góra</td>
<td>Antideprimal</td>
<td>50 mg</td>
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<td>Poland</td>
<td>Krka d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia</td>
<td>Asentra</td>
<td>50 mg</td>
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<td>Oral use</td>
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<td>Asentra</td>
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<td>Oral use</td>
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<td>Pfizer European Service Center N.V./S.A.; Central and Eastern Europe Region, Hoge Wei 10, B-1930 Zaventem, BE</td>
<td>Zoloft</td>
<td>20mg/ml</td>
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<td>Pfizer European Service Center N.V./S.A.; Central and Eastern Europe Region, Hoge Wei 10, B-1930 Zaventem, BE</td>
<td>Zoloft</td>
<td>100 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Pfizer European Service Center N.V./S.A.; Central and Eastern Europe Region, Hoge Wei 10, B-1930 Zaventem, BE</td>
<td>Zoloft</td>
<td>50 mg</td>
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<td>Poland</td>
<td>Ratiopharm GmbH, Graf-Arco-Strasse 3, 89-079 Ulm, DE</td>
<td>Setaratio 100</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Tralix 50</td>
<td>50 mg</td>
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<td>Oral use</td>
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<td>Alodial Farmacêutica - Comércio de Produtos Farmacêuticos, Lda., Zemouto 2830 Coina Portugal</td>
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<td>100 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Oral use</td>
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<td>Oral use</td>
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<td>Alter, S.A., Estrada Marco do Grilo - Zemouto 2830 Coina Portugal</td>
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<td>Alter, S.A., Estrada Marco do Grilo - Zemouto 2830 Coina Portugal</td>
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<td>Bexal Produtos Farmacêuticos S.A., Rua Prof. Ricardo Jorge, 5 A - Miraflores 1495-153 Algés Portugal</td>
<td>Sertralina Bexal 100 mg Comprimidos revestidos</td>
<td>100 mg</td>
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<td>Oral use</td>
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<td>Bexal Produtos Farmacêuticos S.A., Rua Prof. Ricardo Jorge, 5 A - Miraflores 1495-153 Algés Portugal</td>
<td>Sertralina Bexal 50 mg Comprimidos revestidos</td>
<td>50 mg</td>
<td>Coated tablet</td>
<td>Oral use</td>
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<td>Portugal</td>
<td>Ciclum Farma Unipessoal, Lda., Rua Alfredo da Silva, nº 16 2610-016 Amadora Portugal</td>
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<td>50 mg</td>
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<td>Generis Farmacêutica, S.A., Rua José Galhardo, n.º 3 1750-131 Lisboa Portugal</td>
<td>Sertralina Generis 100 mg Comprimidos Revestidos</td>
<td>100 mg</td>
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<td>Generis Farmacêutica, S.A., Rua José Galhardo, n.º 3 1750-131 Lisboa Portugal</td>
<td>Sertralina Generis 50 mg Comprimidos Revestidos</td>
<td>50 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Portugal</td>
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<td>Zoloft</td>
<td>50 mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Laboratórios Pfizer, Lda., Lagoas Park - Edificio nº 10 2740-244 Porto Salvo Portugal</td>
<td>Zoloft</td>
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<td>Film-coated tablet</td>
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<td>Zoloft</td>
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<td>Sertralina Merck Genéricos 100 mg Comprimidos Revestidos</td>
<td>100 mg</td>
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<td>Merck Genéricos - Produtos Farmacêuticos, Lda., Rua Alfredo da Silva, 3 - C - 4º 1300-040 Lisboa Portugal</td>
<td>Sertralina Merck Genéricos 50 mg Comprimidos Revestidos</td>
<td>50 mg</td>
<td>Film-coated tablet</td>
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<td>Member State</td>
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<td>Strength</td>
<td>Pharmaceutical form</td>
<td>Route of administration</td>
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<td>Sertralina ratiopharm 100 mg Comprimidos Revestidos</td>
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<td>Oral use</td>
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<td>Winthrop Farmacêutica Portugal, Lda. Empreendimento Lagoas Park - Edifício 7, 2º e 3º andar 2740-244 Porto Salvo Portugal</td>
<td>Sertralina Winthrop 100 mg Comprimidos Revestidos por película</td>
<td>100 mg</td>
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<td>A/S GEA Farmaceut. Fabrik, Holger Danskaes Vej 89, DK - 2000 Frederiksberg</td>
<td>SETRALEXIN 100</td>
<td>100mg</td>
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<td>SETRALEXIN 50</td>
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<td>EGIS Pharmaceuticals Ltd., Keresztúri út 30-38, HU- 1160 Budapest</td>
<td>STIMULOTON 50mg</td>
<td>50mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Slovak Republic</td>
<td>Pfizer Limited, Ramsgate Road, Sandwich Kent CT13 9NJ UNITED KINGDOM</td>
<td>ZOLOFT OC 20mg/ml</td>
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<td>Concentrate for solution for infusion</td>
<td>Intravenous use</td>
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<td>Pfizer Limited, Sandwich Kent CT13 9NJ UNITED KINGDOM</td>
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<td>Film-coated tablet</td>
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<td>Slovak Republic</td>
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<td>100mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Slovak Republic</td>
<td>Ranbaxy (UK) Ltd, C.P.House, 97-107 Uxbridge Road, Eabing,, UK - London, W5 5TL</td>
<td>SERLIFT 100mg</td>
<td>100mg</td>
<td>Film-coated tablet</td>
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<td>SERLIFT 50mg</td>
<td>50mg</td>
<td>Film-coated tablet</td>
<td>Oral use</td>
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<td>Slovak Republic</td>
<td>Ratiopharm GmbH , Gras-Orco-Strasse 3, D - 890 79 Ulm</td>
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<td>Strength</td>
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<td>50mg</td>
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<td>Oral use</td>
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<td>Film-coated tablet</td>
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<td>100 mg</td>
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<td>Slovenia</td>
<td>KRKA, tovarna zdravil, d.d., Novo mesto, Šmarješka cesta 6, SI-8501 Novo mesto, Slovenia</td>
<td>ASENTRA 50 mg</td>
<td>50 mg</td>
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<td>Spain</td>
<td>MERCK GENERICOS, S.L, CTRA.N-152,KM 19 - POLiGONO MERCK, 08100 Mollet del Valles, Spain</td>
<td>SERTRALINA MERCK</td>
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<td>Strength</td>
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**VENLAFAXINE containing medicinal products with Marketing Authorisation in the European Union**

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<td>John Wyeth &amp; Sons Limited, Huntercombe Lane South, Taplow, Maidenhead, Berks SL6 0PH, UK</td>
<td>Efexor</td>
<td>50mg</td>
<td>Tablet</td>
<td>Oral use</td>
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<td>Efexor XL</td>
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<td>Modified Release Capsule, hard</td>
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ANNEX II

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR AMENDMENT OF THE SUMMARIES OF PRODUCT CHARACTERISTICS AND PACKAGE LEAFLETS PRESENTED BY THE EMEA
SCIENTIFIC CONCLUSIONS

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF MEDICINAL PRODUCTS CONTAINING FLUOXETINE, FLUVOXAMINE, SERTRALINE, PAROXETINE, CITALOPRAM, ESCITALOPRAM, ATOMOXETINE, VENLAFAXINE, MIANSERINE, MILNACIPRAN, REBOXETINE AND MIRTAZAPINE (see Annex I)

Following a request from the European Commission, the CHMP reviewed the data from clinical trials available to the national competent authorities for the following SSRI\(^1\)/SNRIs\(^2\) products particularly as regards their use in the paediatric population: fluoxetine, fluvoxamine, sertraline, paroxetine, citalopram, escitalopram, atomoxetine, duloxetine, venlafaxine, mianserine, milnacipran, reboxetine, and mirtazapine.

The data reviewed included short-term placebo controlled randomised clinical trials submitted to the competent authorities, randomised clinical trials published in the medical literature, observational studies and ecological studies. The majority of trials included patients with major depressive disorders (MDD) while a few included patients with various anxiety disorders (Obsessive Compulsive Disorder (OCD), Generalised Anxiety Disorder (GAD), and Social Anxiety Disorder (SAD)). In addition there were some trials with patients suffering from Attention Deficit/Hyperactivity Disorder (ADHD).

These products are not authorised Europe-wide for the treatment of depression and anxiety disorders in children or adolescents. Only some of these products are authorised for the treatment of children and adolescents with obsessive-compulsive disorder and only one of them for the treatment of Attention Deficit/Hyperactivity Disorder.

Examination of suicide-related behaviours indicated that no completed suicide was reported in any of the reviewed studies. However, there was a clear suicide-related behaviours signal from the depression studies and a less strong signal from the anxiety studies. Moreover there was a signal concerning related adverse events like hostility, self-harm and emotional lability in almost all products and indications.

With the preliminary review of the data available to the national competent authorities the CHMP concluded that there were grounds for concerns about increased suicide-related behaviours in paediatric populations. The CHMP agreed that there was a potential signal of an increase in suicidal behaviour, including suicide attempts and suicidal ideation and/or related behaviour like self-harm, hostility and mood lability in children and adolescents treated with SSRIs and SNRIs. This signal was present in all products for which studies were available, and from the available evidence it could not be excluded that this signal would be class related.

Following the review of the data available to the national competent authorities, the European Commission triggered an article 31 of Directive 2001/83/EC, as amended, on 17 December 2004. The EC requested the CHMP to give its opinion on whether the marketing authorisation for medicinal products containing the above mentioned active substances should be maintained, varied, suspended or withdrawn.

\(^1\) SSRI stands for ‘Serotonin-Selective Reuptake Inhibitor’. SSRIs are described as ‘selective’ because they affect only the reuptake pumps responsible for serotonin.

\(^2\) SNRI stands for ‘Serotonin-Norepinephrine Reuptake Inhibitor’. SNRIs work on the norepinephrine and serotonin neurotransmitters.
The CHMP reviewed the data submitted by the MAHs in relation to the signal of suicidal behaviour in children and adolescents. The CHMP concluded that a warning to reflect that suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo, should be included in the Summaries of Product Characteristics and relevant section of the Package Leaflets of citalopram, escitalopram, fluoxetine, fluvoxamine, mianserine, milnacipran, mirtazapine, paroxetine, reboxetine, sertraline and venlafaxine containing medicinal products.

The Committee also concluded that a different warning was more appropriate for atomoxetine, which is only indicated in the treatment of ADHD. The CHMP considered that there wasn’t any signal of increased risk of suicide related behaviour in the atomoxetine studies, however, there was a signal of an increased risk of behavioural abnormalities with more aggression and hostility effects. Therefore the CHMP concluded that a warning to reflect that hostility (predominantly aggression, oppositional behaviour and anger) and emotional lability were more frequently observed in clinical trials among children and adolescents treated with atomoxetine compared to those treated with placebo and a warning indicating the lack of efficacy in depression should be included in the Summaries of Product Characteristics and the relevant section of the Package Leaflets of atomoxetine containing medicinal products.
GROUND FOR AMENDMENT OF THE SUMMARIES OF PRODUCT CHARACTERISTICS

Whereas

- The Committee considered the referral made under article 31 of Directive 2001/83/EC, as amended, for medicinal products containing atomoxetine, citalopram, escitalopram, fluoxetine, fluvoxamine, mianserine, milnacipran, mirtazapine, paroxetine, reboxetine, sertraline and venlafaxine;

- The Committee, in view of available data from clinical trials, concluded that there is a signal of suicidal behaviour, including suicide attempts and suicidal ideation and/or related behaviour like self-harm, hostility and mood lability in children and adolescents treated with Selective Serotonin Reuptake Inhibitors and Serotonin-Norepinephrine Reuptake Inhibitors, such as the medicinal products mentioned above;

- The Committee, as a consequence, concluded that a warning to reflect that suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo, should be included in the Summaries of Product Characteristics and relevant section of the Package Leaflets of citalopram, escitalopram, fluoxetine, fluvoxamine, mianserine, milnacipran, mirtazapine, paroxetine, reboxetine, sertraline and venlafaxine containing medicinal products.

- For atomoxetine, which is only indicated in the treatment of ADHD, the Committee concluded that a warning to reflect that hostility (predominantly aggression, oppositional behaviour and anger), and emotional lability were more frequently observed in clinical trials among children and adolescents treated with atomoxetine compared to those treated with placebo and a warning indicating the lack of efficacy in depression should be included in the Summaries of Product Characteristics and relevant section of the Package Leaflets of atomoxetine containing medicinal products.

The CHMP has recommended the maintenance of the Marketing Authorisations for the medicinal products referred to in Annex I for which the amendments to the relevant sections of the Summary of Product Characteristics and Package Leaflets are set out respectively in Annexes III and IV.
ANNEX III

AMENDMENTS TO THE
SUMMARY OF PRODUCT CHARACTERISTICS

Note: This section of the Summary of Product Characteristics is the one that was Annexed to the Commission Decision on this Article 31 referral. The text was valid at that time.

After the Commission Decision, the Member State competent authorities will update the product information as required. Therefore, this wording may not necessarily represent the current text.
III.1 AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTION OF THE SPC FOR FLUOXETINE, FLUVOXAMINE, SERTRALINE, PAROXETINE, CITALOPRAM, ESCITALOPRAM, VENLAFAXINE, MIANSERINE, MILNACIPRAN, REBOXETINE AND MIRTAZAPINE

4.4 Special warnings and Special precautions for use

[………]
Use in children and adolescents under 18 years of age
[Invented Name] should not be used in the treatment of children and adolescents under the age of 18 years <, except for patients with [approved indication]>. Suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking.

[………]

III.2 AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTION OF THE SPC FOR ATOMOXETINE

4.4 Special warnings and precautions for use

[………]
Hostility (predominantly aggression, oppositional behaviour and anger) and emotional lability were more frequently observed in clinical trials among children and adolescents treated with [Invented Name] compared to those treated with placebo. Patients beginning treatment for ADHD should be carefully monitored for the appearance or worsening of hostility and emotional lability. As with other psychotropic medication, the possibility of rare, serious psychiatric adverse effects cannot be excluded.

[………]
[Invented Name] is not indicated for the treatment of major depressive episodes and/or anxiety as the results of clinical trials that were conducted in adults did not show any effect compare to placebo, and therefore were negative.

[………]
ANNEX IV

AMENDMENTS TO THE
PACKAGE LEAFLET

Note: This section of the Package Leaflet is the one that was Annexed to the Commission Decision on this Article 31 referral. The text was valid at that time.

After the Commission Decision, the Member State competent authorities will update the product information as required. Therefore, this wording may not necessarily represent the current text.
IV.1 AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTION OF THE PACKAGE LEAFLET FOR FLUOXETINE, FLUVOXAMINE, SERTRALINE, PAROXETINE, CITALOPRAM, ESCITALOPRAM, VENLAFAXINE, MIANSERINE, MILNACIPRAN, REBOXETINE AND MIRTAZAPINE

[........]
Use in children and adolescents under 18 years of age
[Invented Name] should normally not be used for children and adolescents under 18 years < except for patients with [approved indication]>. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe [Invented Name] for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed [Invented Name] for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking [Invented Name]. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of [Invented Name] in this age group have not yet been demonstrated.

[........]

IV.2 AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTION OF THE PL FOR ATOMOXETINE

[........]
Patients under 18 have an increased risk of side-effects such as hostility (predominantly aggression, oppositional behaviour and anger) and emotional lability. You should inform your doctor if any of the symptoms listed above develop or worsen after treatment has begun. Also you should know that as with other psychotropics medication, the possibility of rare, serious psychiatric adverse effects cannot be excluded. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of [Invented Name] in this age group have not yet been demonstrated.

[........]