

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES AND NORWAY AND ICELAND

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Austria	Pfizer Corporation Austria Gesmbh Floridsdorfer Hauptstraße 1 1210 Wien Austria	Felden - Gel		Gel	Cutaneous use
Austria	Pfizer Corporation Austria Gesmbh Floridsdorfer Hauptstraße 1 1210 Wien Austria	Felden 20 Mg - Ampullen	20 mg	Ampoule	Parenteral use
Austria	Pfizer Corporation Austria Gesmbh Floridsdorfer Hauptstraße 1 1210 Wien Austria	Felden 20 Mg - Kapseln	10 mg	Capsule	Oral use
Austria	Pfizer Corporation Austria Gesmbh Floridsdorfer Hauptstraße 1 1210 Wien Austria	Felden 20 Mg - Kapseln	20 mg	Capsule	Oral use
Austria	Pfizer Corporation Austria Gesmbh Floridsdorfer Hauptstraße 1 1210 Wien Austria	Felden 20 Mg - Lösbare Tabletten	20 mg	Tablet	Oral use
Austria	Pfizer Corporation Austria Gesmbh Floridsdorfer Hauptstraße 1 1210 Wien Austria	Felden Quick - Solve 20 Mg - Lyotabletten	20 mg	Tablet	Oral use
Austria	Ratiopharm Arzneimittel Vertriebs-GmbH Albert - Schweitzer - Gasse 3 1140 Wien Austria	Pirocam 20 Mg - Ampullen	20 mg	Ampoule	Parenteral use
Austria	Ratiopharm Arzneimittel Vertriebs-GmbH Albert - Schweitzer - Gasse 3 1140 Wien Austria	Pirocam 20 Mg - Tabletten	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Austria	Ratiopharm Arzneimittel Vertriebs-GmbH Albert - Schweitzer - Gasse 3 1140 Wien Austria	Pirocam 20 Mg - Zäpfchen	20 mg	Suppository	Rectal use
Austria	Hexal Pharma GmbH Carlberggasse 44 1235 Wien Austria	Pirorheum 10 Mg - Tabletten	10 mg	Tablet	Oral use
Austria	Hexal Pharma GmbH Carlberggasse 44 1235 Wien Austria	Pirorheum 20 Mg - Tabletten	20 mg	Tablet	Oral use
Austria	Ci Pharma Arzneimittel HandelsgesmbH Thimiggasse 25 1180 Wien Austria	Piroxicam 'Ci Pharma' 20 Mg - Brausepulver	20 mg	Effervescent Powder	Oral use
Austria	Stada Arzneimittel GmbH. Heiligenstädterstraße 52/2/8 1190 Wien Austria	Piroxistad 10 Mg Tabs - Lösbare Tabletten	10 mg	Tablet	Oral use
Austria	Stada Arzneimittel GmbH. Heiligenstädterstraße 52/2/8 1190 Wien Austria	Piroxistad 20 Mg Tabs - Lösbare Tabletten	20 mg	Tablet	Oral use
Austria	Amat Pharma Trading GmbH Walfischgasse 6/2/1/3 1010 Wien Austria	Pirox 10 Mg - Kapseln	10 mg	Capsule	Oral use
Austria	Amat Pharma Trading GmbH Walfischgasse 6/2/1/3 1010 Wien Austria	Pirox 20 Mg - Kapseln	20 mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Austria	Amat Pharma Trading Gmbh Walfischgasse 6/2/1/3 1010 Wien Austria	Pirox 0,2% - Orale Suspension	2 mg/ml	Oral Suspension	Oral use
Austria	Boehringer Ingelheim Austria Gmbh. Dr. Boehringer - Gasse 5-11 1121 Wien Austria	Tonimed - Gel		Gel	Topical use
Austria	Torrex-Chiesi Pharma Gmbh. Gonzagagasse 16/16 A-1010 Wien Austria	Brexin 20 Mg – Tabletten	20 mg	Tablets	Oral use
Austria	Torrex-Chiesi Pharma Gmbh. Gonzagagasse 16/16 A-1010 Wien Austria	Brexin -Pulver	20 mg	Oral powder	Oral use
Belgium	3ddd Pharma N.N. Diestersteenweg 349 B-3510 Hasselt Belgium	Piromed	0.50%	Gel	Transdermal use
Belgium	3ddd Pharma N.N. Diestersteenweg 349 B-3510 Hasselt Belgium	Piromed Dispers	20 mg	Tablet	Oral use
Belgium	Aktuapharma N.V. Ambachtenlaan 13e B-3001 Leuven Belgium	Brexine	20 mg	Tablet	Oral use
Belgium	Aktuapharma N.V. Ambachtenlaan 13e B-3001 Leuven Belgium	Brexine	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Belgium	Aktuapharma N.V. Ambachtenlaan 13e B-3001 Leuven Belgium	Feldene Dispersal	20 mg	Tablet	Oral use
Belgium	Aktuapharma N.V. Ambachtenlaan 13e B-3001 Leuven Belgium	Feldene	20 mg	Capsule	Oral use
Belgium	Aktuapharma N.V. Ambachtenlaan 13e B-3001 Leuven Belgium	Feldene Im	20 mg/ml	Solution for injection	Intramuscular use
Belgium	Aktuapharma N.V. Ambachtenlaan 13e B-3001 Leuven Belgium	Feldene Lyotabs	20 mg	Lyophilisat	Oral use
Belgium	Aktuapharma N.V. Ambachtenlaan 13e B-3001 Leuven Belgium	Piroxicam Eg	20 mg	Capsule	Oral use
Belgium	Bexal S.P.R.L. Avenue Jules Bordet 168 B-1140 Brussels Belgium	Piroxicam Bexal	10 mg	Tablet	Oral use
Belgium	Bexal S.P.R.L. Avenue Jules Bordet 168 B-1140 Brussels Belgium	Piroxicam Bexal	20 mg	Tablet	Oral use
Belgium	Docpharma N.V. Ambachtenlaan B-3001 Heverlee Belgium	Dociproxi Dispers Ex Piroxicam	20 mg	Dispersible tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Belgium	Ethimed N.V. Leuvensestraat 28 Bus 2 B-1800 Vilvoorde Belgium	Piroxymed	20 mg	Dispersible tablet	Oral use
Belgium	Eurogenerics N.V. Heizel Esplanade 22 B-1020 Brussels Belgium	Piroxicam Eg	10 mg	Capsule	Oral use
Belgium	Eurogenerics N.V. Heizel Esplanade 22 B-1020 Brussels Belgium	Piroxicam Eg	20 mg	Capsule	Oral use
Belgium	Eurogenerics N.V. Heizel Esplanade 22 B-1020 Brussels Belgium	Piroxicam Eg	20 mg	Dispersible tablet	Oral use
Belgium	Eurogenerics N.V. Heizel Esplanade 22 B-1020 Brussels Belgium	Piroxicam Eg	20 mg/ml	Solution for injection	Intramuscular use
Belgium	Eurogenerics N.V. Heizel Esplanade 22 B-1020 Brussels Belgium	Piroxicam Generix	20 mg	Dispersible tablet	Oral use
Belgium	Eurogenerics N.V. Heizel Esplanade 22 B-1020 Brussels Belgium	Piroxicam Generix	20 mg	Capsule	Oral use
Belgium	Eurogenerics N.V. Heizel Esplanade 22 B-1020 Brussels Belgium	Piroxicam- Ratiopharm	20 mg	Solution for injection	Intramuscular use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Belgium	Eurogenerics N.V. Heizel Esplanade 22 B-1020 Brussels Belgium	Piroxicamstada	20 mg	Capsule	Oral use
Belgium	Euro-Medic N.V. Astridlaan 20 B-8620 Nieuwpoort Belgium	Brexine	20 mg	Tablet	Oral use
Belgium	Euro-Medic N.V. Astridlaan 20 B-8620 Nieuwpoort Belgium	Feldene Lyotabs	20 mg	Tablet	Oral use
Belgium	Kela Laboratoria N.V. Sint Lenaartseweg 48/4 B-2320 Hoogstraten Belgium	Piroxicam Kela Ex Revalat	20 mg	Dispersible tablet	Oral use
Belgium	Laboratoires S.M.B S. S.A. Rue De La Pastorale 16/28 B-1080 Brussels Belgium	Solicam	10 mg	Capsule	Oral use
Belgium	Laboratoires S.M.B S. S.A. Rue De La Pastorale 16/28 B-1080 Brussels Belgium	Solicam	20 mg	Capsule	Oral use
Belgium	Merck N.V. Brusselsesteenweg 288 B-3090 Overijse Belgium	Merck-Piroxicam	20 mg	Capsule	Oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 B-1080 Brussels Belgium	Brexine	10 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 B-1080 Brussels Belgium	Brexine - Dryfiz Ex Piroxidex	20 mg	Tablet	Oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 B-1080 Brussels Belgium	Brexine	20 mg	Granules	Oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 B-1080 Brussels Belgium	Brexine	20 mg	Tablet	Oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 B-1080 Brussels Belgium	Piroxidex	20 mg	Dispersible tablet	Oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 B-1080 Brussels Belgium	Piroxidex	20 mg	Powder	Oral use
Belgium	Pfizer S.A., Boulevard De La Plaine 17 B-1050 Brussels Belgium	Feldene	20 mg	Capsule	Oral use
Belgium	Pfizer S.A., Boulevard De La Plaine 17 B-1050 Brussels Belgium	Feldene	10 mg	Capsule	Oral use
Belgium	Pfizer S.A., Boulevard De La Plaine 17 B-1050 Brussels Belgium	Feldene	20 mg	Suppository	Rectal use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Belgium	Pfizer S.A., Boulevard De La Plaine 17 B-1050 Brussels Belgium	Feldene	0.50%	Gel	Transdermal use
Belgium	Pfizer S.A., Boulevard De La Plaine 17 B-1050 Brussels Belgium	Feldene	20 mg/ml	Solution for injection	Intramuscular use
Belgium	Pfizer S.A., Boulevard De La Plaine 17 B-1050 Brussels Belgium	Feldene Dispersal	20 mg	Tablet	Oral use
Belgium	Pfizer S.A., Boulevard De La Plaine 17 B-1050 Brussels Belgium	Feldene Lyotabs	10 mg	Lyophilisat	Oral use
Belgium	Pfizer S.A., Boulevard De La Plaine 17 B-1050 Brussels Belgium	Feldene Lyotabs	20 mg	Lyophilisat	Oral use
Belgium	Pharmapartner Nv Kolonel Begaultlaan 16 B-3012 Leuven Belgium	Feldene Lyotabs	20 mg	Tablet	Oral use
Belgium	Ratiopharm Belgium S.A. Rue Saint-Lambert 141 B-1200 Bruxelles Belgium	Piroxicam - Ratiopharm	20 mg	Suppository	Rectal use
Belgium	Ratiopharm Belgium S.A. Rue Saint-Lambert 141 B-1200 Bruxelles Belgium	Piroxicam- Ratiopharm	10 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Belgium	Ratiopharm Belgium S.A. Rue Saint-Lambert 141 B-1200 Bruxelles Belgium	Piroxicam- Ratiopharm	20 mg	Tablet	Oral use
Belgium	Sandoz N.V. Telecom Ardens - Medialaan 40 B-1800 Vilvoorde Belgium	Piroxicam Sandoz	20 mg	Dispersible tablet	Oral use
Belgium	Socobom N.V. Luoizalaan 149 Bus 4 B-1050 Brussels Belgium	Polydene	20 mg	Dispersible tablet	Oral use
Belgium	Teva Generics Belgium N.V. Laarstraat 16 B-2610 Wilrijk Belgium	Piroxicam Teva	10 mg	Capsule	Oral use
Belgium	Teva Generics Belgium N.V. Laarstraat 16 B-2610 Wilrijk Belgium	Piroxicam Teva	20 mg	Suppository	Rectal use
Belgium	Teva Generics Belgium N.V. Laarstraat 16 B-2610 Wilrijk Belgium	Piroxicam Teva	20 mg	Capsule	Oral use
Belgium	Teva Generics Belgium N.V. Laarstraat 16 B-2610 Wilrijk Belgium	Piroxicam Teva	20 mg	Dispersible tablet	Oral use
Belgium	Topgen Esv E.Demunterlaan 1/8 B-1090 Brussels Belgium	Piroxitop	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Belgium	P.S.I. N.V. Kraanlei 27-29 B-900 Gent Belgium	Veralgesic	20 mg	Dispersible tablet	Oral use
Bulgaria	Alkaloid Ltd 21 "Tzar Boris III" Blvd., 1000 Sofia Bulgaria	Piroxicam Alkaloid	20mg	Capsule	Oral use
Bulgaria	Sopharma AD 16 "Iliensko Shose" str. 1220 Sofia Bulgaria	Piroxicam Sopharma	10 mg	Capsule, hard	Oral use
Bulgaria	Sopharma AD 16 "Iliensko Shose" str. 1220 Sofia Bulgaria	Piroxicam Sopharma	20 mg	Capsule, hard	Oral use
Bulgaria	Sopharma AD 16 "Iliensko Shose" str. 1220 Sofia Bulgaria	Piroxicam Sopharma 1%	1 g/100 g - 40g	Gel	Cutaneous use
Bulgaria	Sopharma AD 16 "Iliensko Shose" str. 1220 Sofia Bulgaria	Piroxicam Sopharma 0.5%	0.5g/100g - 40g	Gel	Cutaneous use
Bulgaria	Boehringer Ingelheim International GmbH Binger Strasse 173 D-55216 Ingelheim am Rhein Germany	Finalgel	0.5g/100g - 35g; 50g	Gel	Cutaneous use
Bulgaria	Promedica S.p.A. Via Palermo 26 A 43100, Parma Italy	Flamexin	20mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Bulgaria	Promedica S.p.A. Via Palermo 26 A 43100, Parma Italy	Flamexin	20 mg	Powder for oral solution	Oral use
Bulgaria	Egis Pharmaceuticals Public Limited Company Kereszturi ut 30-38 H-1106 Budapest Hungary	Hotemin 10 mg capsule	10 mg	Capsule	Oral use
Bulgaria	Egis Pharmaceuticals Public Limited Company Kereszturi ut 30-38 H-1106 Budapest Hungary	Hotemin 20 mg capsule	20 mg	Capsule	Oral use
Bulgaria	Egis Pharmaceuticals Public Limited Company Kereszturi ut 30-38 H-1106 Budapest Hungary	Hotemin Injection	20 mg/ml -1ml	Solution for injection	Intramuscular use
Bulgaria	Egis Pharmaceuticals Public Limited Company Kereszturi ut 30-38 H-1106 Budapest Hungary	Hotemin	20 mg	Suppository	Rectal use
Bulgaria	Egis Pharmaceuticals Public Limited Company Kereszturi ut 30-38 H-1106 Budapest Hungary	Hotemin	10 mg	Suppository	Rectal use
Bulgaria	Egis Pharmaceuticals Public Limited Company Kereszturi ut 30-38 H-1106 Budapest Hungary	Hotemin	0.5g/50g - 50g	Cream	Cutaneous use
Cyprus	Pfizer Hellas Ae 243 Mesogion Ave, 15451 N. Psychiko Greece	Feldene	10 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Cyprus	Pfizer Hellas Ae 243 Mesogion Ave, 15451 N. Psychiko Greece	Feldene	20 mg	Dispersible tablet	Oral use
Cyprus	Pfizer Hellas Ae 243 Mesogion Ave, 15451 N. Psychiko Greece	Feldene	20 mg	Suppository	Rectal use
Cyprus	Pfizer Hellas Ae 243 Mesogion Ave, 15451 N. Psychiko Greece	Feldene	0.50%	Gel	External use
Cyprus	Pfizer Hellas Ae 243 Mesogion Ave, 15451 N. Psychiko Greece	Feldene	20 mg/ml, 1ml	Solution for injection	Intramuscular use
Cyprus	Varnavas Hadjipanayis 7 Androcleous Str. Pobox 21229 1504 Lefkosia Cyprus	Brexin	20 mg	Tablet	Oral use
Cyprus	Medochemie Ltd Pobox 51409, 3505 Lemesos, Cyprus	Sotilen	10 mg	Capsule	Oral use
Cyprus	Medochemie Ltd Pobox 51409, 3505 Lemesos, Cyprus	Sotilen	20 mg	Capsule	Oral use
Cyprus	Medochemie Ltd Pobox 51409, 3505 Lemesos,	Sotilen	1%	Gel	External use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Cyprus	Cyprus Remedica Ltd Limassol Industrial Estate Aharnon Str. P.O Box 51706 3508 Limassol	Roxitan	10 mg	Capsule	Oral use
Cyprus	Cyprus Remedica Ltd Limassol Industrial Estate Aharnon Str. P.O Box 51706 3508 Limassol	Roxitan	20 mg	Capsule	Oral use
Czech Republic	Cyprus Egis Pharmaceuticals Ltd. Keresztúri Út 30-38 1106 Budapest Hungary	Hotemin	20MG/ML	Solution for injection	Intramuscular use
Czech Republic	Egis Pharmaceuticals Ltd. Keresztúri Út 30-38 1106 Budapest Hungary	Hotemin 10 mg,	10 mg	Capsule, hard	Oral use
Czech Republic	Egis Pharmaceuticals Ltd. Keresztúri Út 30-38 1106 Budapest Hungary	Hotemin 20 Mg	20 mg	Capsule, hard	Oral use
Czech Republic	Egis Pharmaceuticals Ltd. Keresztúri Út 30-38 1106 Budapest Hungary	Hotemin	10mg/gm	Cream	Cutaneous use
Czech Republic	Pro.Med.Cs Praha A.S. Telčská 1 14000 Praha 4	Pro-Roxikam 10 mg	10 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Czech Republic	Czech Republic Pro.Med.Cs Praha A.S. Telčská 1 14000 Praha 4 Czech Republic	Pro-Roxikam 20 Mg	20 mg	Tablet	Oral use
Czech Republic	Aliud Pharma Gmbh & Co.Kg. Gottlieb-Daimler-Strasse 19 891 50 Laichingen Germany	Piroxicam Al 10 Piroxicam Al 20	10 mg 20 mg	Tablet	Oral use
Czech Republic	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Flamexin	20 mg	Tablet	Oral use
Czech Republic	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Flamexin	20 mg	Granules	Oral use
Czech Republic	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Flamexin Eff	20 mg	Effervescent tablet	Oral use
Germany	Abz-Pharma Gmbh Dr. Georg-Spohn-Str. 7 D-89143 Blaubeuren Germany	Piro 10mg Abz 10231.00.00	10mg	Tablet	Oral use
Germany	Abz-Pharma Gmbh Dr. Georg-Spohn-Str. 7 D-89143 Blaubeuren Germany	Piro 20mg Abz 10231.01.00	20mg	Tablet	Oral use
Germany	Acis Arzneimittel Gmbh Bajuwarenring 14 D-82041 Oberhaching	Piroxicam Acis 20mg Tabs 29562.00.00	20mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Germany Aliud Pharma Gmbh & Co.Kg Gottlieb-Daimler-Str. 19 D-89150 Laichingen	Piroxicam Al 10 30314.00.00	10mg	Tablet	Oral use
Germany	Germany Aliud Pharma Gmbh & Co.Kg Gottlieb-Daimler-Str. 19 D-89150 Laichingen	Piroxicam Al 20 29583.00.00	20mg	Tablet	Oral use
Germany	Germany Aliud Pharma Gmbh & Co.Kg Gottlieb-Daimler-Str. 19 D-89150 Laichingen	Piroxicam Al 20 Brausetabletten 31544.00.00	20mg	Effervescent tablet	Oral use
Germany	Germany Aliud Pharma Gmbh & Co.Kg Gottlieb-Daimler-Str. 19 D-89150 Laichingen	Piroxicam Al 20 Zäpfchen 6412895.00.00	20mg	Suppository	Rectal use
Germany	Asche Chiesi Gmbh Gasstr. 6 D-22761 Hamburg Germany	Brexidol 20 Mg Granulat Zur Herstellung Einer Lösung Zum Einnehmen 27116.00.01	20mg/3g	Granules	Oral use
Germany	Asche Chiesi Gmbh Gasstr. 6 D-22761 Hamburg Germany	Brexidol 20 Mg Tabletten 27116.00.00	20mg	Tablet	Oral use
Germany	Asche Chiesi Gmbh Gasstr. 6 D-22761 Hamburg Germany	Pc-Fice 20 Mg Granulat Zur Herstellung Einer Lösung Zum Einnehmen 28887.00.01	20mg/3g	Granules	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Asche Chiesi Gmbh Gasstr. 6 D-22761 Hamburg Germany	Pc-Fice 20 Mg Tabletten 28887.00.00	20mg	Tablet	Oral use
Germany	Bc Biochemie Pharma Gmbh Carl-Zeiss-Ring 3 D- 85737 Ismaning Germany	Fasax 10 Mg Tabs 26221.00.00	10mg	Tablet	Oral use
Germany	Bc Biochemie Pharma Gmbh Carl-Zeiss-Ring 3 D- 85737 Ismaning Germany	Fasax 20 Mg Tabs 24902.00.00	20mg	Tablet	Oral use
Germany	Betapharm Arzneimittel Gmbh Kobelweg 95 D-86156 Augsburg Germany	Pirobeta 10 37338.00.00	10mg	Tablet	Oral use
Germany	Betapharm Arzneimittel Gmbh Kobelweg 95 D-86156 Augsburg Germany	Pirobeta 20 37338.01.00	20mg	Tablet	Oral use
Germany	Ct-Arzneimittel Gmbh Lengeder Str. 42a D-13407 Berlin Germany	Pirox-Ct 20mg Tabletten 6156699.01.01	20mg	Tablet	Oral use
Germany	CT-Arzneimittel Gmbh Lengeder Str. 42a D-13407 Berlin Germany	Pirox-CT 20mg/1ml Ampullen 6061697.00.00	20mg/1ml	Solution for injection	Injection
Germany	Docpharm Arznewimittelvertrieb Gmbh & Co.Kгаа Reetzstr. 83 D-76327 Pfinztal Germany	Piroxicam Pb 10mg 26223.00.00	10mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Docpharm Arznewmittelvertrieb Gmbh & Co.Kgaa Reetzstr. 83 D-76327 Pfinztal Germany	Piroxicam Pb 20mg 26223.01.00	20mg	Tablet	Oral use
Germany	Dr. Kade Pharmazeutische Fabrik Gmbh Rigistr. 2 D-12277 Berlin Germany	Piro Kd 10 Tabs 36015.00.00	10mg	Tablet	Oral use
Germany	Dr. Kade Pharmazeutische Fabrik Gmbh Rigistr. 2 D-12277 Berlin Germany	Piro Kd 20 Tabs 34106.01.00	20mg	Tablet	Oral use
Germany	Heumann Pharma Gmbh & Co. Generica Kg Südwestpark 50 D-90449 Nürnberg Germany	Piroxicam 10 Heumann 12426.00.00	10mg	Tablet	Oral use
Germany	Heumann Pharma Gmbh & Co. Generica Kg Südwestpark 50 D-90449 Nürnberg Germany	Piroxicam 20 Heumann 12426.01.00	20mg	Tablet	Oral use
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	A.M. Piroxicam 20 10013.00.00	20mg	Suppository	Rectal use
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Ig 20 I.M. 53304.00.00	20mg/1ml	Solution for injection	Injection
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Maxiflam 20 I.M. 53303.00.00	20mg/1ml	Solution for injection	Injection

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Piro 20 I.M. 53307.00.00	20mg/1ml	Solution for injection	Injection
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Pirorheum 20 I.M. 31511.00.01	20mg/1ml	Solution for injection	Injection
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Piroxicam Hexal 10 Mg Tabs 9625.00.02	10mg	Tablet	Oral use
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Piroxicam Hexal 20 I.M. 53306.00.00	20mg/1ml	Solution for injection	Injection
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Piroxicam Hexal 20 Mg Brausetabletten 31511.00.00	20mg	Effervescent tablet	Oral use
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Piroxicam Hexal 20 Mg Tabs 9625.01.02	20mg	Tablet	Oral use
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Piroxicam Hexal 20 Mg Zäpfchen 9625.00.01	20mg	Suppository	Rectal use
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Piroxicam Hexal 20mg/MI 3000887.00.00	20mg/1ml	Solution for injection	Injection

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Piroxject 20 I.M. 53305.00.00	20mg/1ml	Solution for injection	Injection
Germany	Hexal Ag Industriestr. 25 D-83607 Holzkirchen Germany	Traumahexal 20 29785.00.00	20mg	Suppository	Rectal use
Germany	Kohne Pharma Gmbh Schallbruch 1 D-42781 Haan Germany	Piroxicam 20 Mg Ako 37588.00.00	20mg	Tablet	Oral use
Germany	Merck Dura Gmbh Alsfelder Str. 19 D-64289 Darmstadt Germany	Durapirox 20mg 12638.00.00	20mg	Capsule	Oral use
Germany	Merck Dura Gmbh Alsfelder Str. 19 D-64289 Darmstadt Germany	Durapirox 20mg Tabs 9627.01.01	20mg	Tablet	Oral use
Germany	Mibe Gmbh Arzneimittel Münchener Str. 15 D- 06796 Brehna Germany	Pirocutan 10mg 29562.01.00	10mg	Tablet	Oral use
Germany	Mibe Gmbh Arzneimittel Münchener Str. 15 D- 06796 Brehna Germany	Pirocutan 20mg 39340.00.00	20mg	Tablet	Oral use
Germany	Mibe Gmbh Arzneimittel Münchener Str. 15 D- 06796 Brehna Germany	Pirocutan Ampullen 6829336.00.00	20mg/1ml	Solution for injection	Injection

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Mibe Gmbh Arzneimittel Münchener Str. 15 D- 06796 Brehna Germany	Pirocutan Ampullen Mibe 48754.00.00	20mg/1ml	Solution for injection	Injection
Germany	Mibe Vertriebsgesellschaft Mbh Otto-Schott-Str. 15 D-07745 Jena Germany	Jenapirox I.M. 20 Mg 6413185.00.00	20mg/1ml	Solution for injection	Injection
Germany	Mibe Vertriebsgesellschaft Mbh Otto-Schott-Str. 15 D-07745 Jena Germany	Jenapirox Tabs 10mg 12637.00.00	10mg	Tablet	Oral use
Germany	Mibe Vertriebsgesellschaft Mbh Otto-Schott-Str. 15 D-07745 Jena Germany	Jenapirox Tabs 20 Mg 9628.00.00	20mg	Tablet	Oral use
Germany	Mibe Vertriebsgesellschaft Mbh Otto-Schott-Str. 15 D-07745 Jena Germany	Piroxicam-Kapseln 10 Mg Jenapharm 41597.00.00	10mg	Capsule	Oral use
Germany	Mibe Vertriebsgesellschaft Mbh Otto-Schott-Str. 15 D-07745 Jena Germany	Piroxicam-Kapseln 10 Mg Jenapharm 6000413.01.00	10mg	Capsule	Oral use
Germany	Mibe Vertriebsgesellschaft Mbh Otto-Schott-Str. 15 D-07745 Jena Germany	Piroxicam-Kapseln 20 Mg Jenapharm 41597.01.00	20mg	Capsule	Oral use
Germany	Mibe Vertriebsgesellschaft Mbh Otto-Schott-Str. 15 D-07745 Jena Germany	Piroxicam-Kapseln 20 Mg Jenapharm 6000413.00.00	20mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Pfizer Pharma Gmbh Pfizerstr. 1 D-76139 Karlsruhe Germany	Felden 20mg Tabs 871.01.02	20mg	Tablet	Oral use
Germany	Ratiopharm Gmbh Graf-Arco-Str. 3 D-89079 Ulm Germany	Piroxicam- Ratiopharm 10 Mg Tabs 6013244.01.00	10mg	Tablet	Oral use
Germany	Ratiopharm Gmbh Graf-Arco-Str. 3 D-89079 Ulm Germany	Piroxicam- Ratiopharm 20 Mg Injektionslösung 6362849.00.00	20mg/1ml	Solution for injection	Injection
Germany	Ratiopharm Gmbh Graf-Arco-Str. 3 D-89079 Ulm Germany	Piroxicam- Ratiopharm 20 Mg Tabs 6013244.00.00	20mg	Tablet	Oral use
Germany	Ratiopharm Gmbh Graf-Arco-Str. 3 D-89079 Ulm Germany	Piroxicam- Ratiopharm 20 Zäpfchen 6040355.00.00	20mg	Suppository	Rectal use
Germany	Ratiopharm Gmbh Graf-Arco-Str. 3 D-89079 Ulm Germany	Piroxicam- Ratiopharm 20mg Zäpfchen 10231.00.01	20mg	Suppository	Rectal use
Germany	Sandoz Pharmaceuticals Gmbh Carl-Zeiss-Ring 3 D-85737 Ismaning Germany	Piroxicam Sandoz Parenteral 20mg Injektionslösung 6139399.00.00	20mg/1ml	Solution for injection	Injection
Germany	Sandoz Pharmaceuticals Gmbh Carl-Zeiss-Ring 3 D-85737 Ismaning Germany	Piroxicam-Ac Suppos 20 30064.00.00	20mg	Suppository	Rectal use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Sandoz Pharmaceuticals Gmbh Carl-Zeiss-Ring 3 D-85737 Ismaning Germany	Piroxicam-Sandoz Parenteral 20 Mg Injektionslösung 53301.00.00	20mg/1ml	Solution for injection	Injection
Germany	Siemens & Co Heilwasser Und Quellenprodukte Des Staatsbades Bad Ems Gmbh & Co.KgArzbacher Str. 78D- 56130 Bad Ems Germany	Piroxicam Hexal 10mg Tabletten 9627.00.01	10mg	Tablet	Oral use
Germany	Siemens & Co Heilwasser Und Quellenprodukte Des Staatsbades Bad Ems Gmbh & Co.Kg Arzbacher Str. 78 D-56130 Bad Ems Germany	Piroxicam Hexal 20mg Tabletten 3000886.01.00	20mg	Tablet	Oral use
Germany	Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel Germany	Piroxi 10 Stada Tabs 44091.00.00	10mg	Tablet	Oral use
Germany	Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel Germany	Piroxi 20 Stada Tabs 44091.01.00	20mg	Tablet	Oral use
Germany	Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel Germany	Piroxicam Stada 6346224.00.00	20mg/1ml	Solution for injection	Injection
Germany	Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel Germany	Piroxicam Stada 10 Mg Kapseln 23046.00.00	10mg	Capsule	Oral use
Germany	Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel	Piroxicam Stada 10mg Tabs 6068067.00.00	10mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Germany Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel	Piroxicam Stada 20 Mg Kapseln 23046.01.00	20mg	Capsule	Oral use
Germany	Germany Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel	Piroxicam Stada 20mg Brausetabletten 39728.00.00	20mg	Effervescent tablet	Oral use
Germany	Germany Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel	Piroxicam Stada 20mg Tabs 6068067.01.00	20mg	Tablet	Oral use
Germany	Germany Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel	Piroxistad Injektionslösung 20 Mg/MI 48755.00.00	20mg/1ml	Solution for injection	Injection
Germany	Germany Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel	Pxi-10 Stada Tabs 28449.00.00	10mg	Tablet	Oral use
Germany	Germany Stada Gmbh Stadastr. 2-18 D-61118 Bad Vilbel	Pxi-20 Stada Tabs 28449.01.00	20mg	Tablet	Oral use
Germany	Germany Tad Pharma Gmbh Heinz-Lohmann-Str. 5 D-27472 Cuxhaven	Flexase 10 Tabs 6691665.00.00	10mg	Tablet	Oral use
Germany	Germany Tad Pharma Gmbh Heinz-Lohmann-Str. 5 D-27472 Cuxhaven	Flexase 10mg Tabs 9625.00.00	10mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Germany Tad Pharma Gmbh Heinz-Lohmann-Str. 5 D-27472 Cuxhaven	Flexase 20mg Tabs 9626.00.00	20mg	Tablet	Oral use
Germany	Germany Tad Pharma Gmbh Heinz-Lohmann-Str. 5 D-27472 Cuxhaven	Flexase Ampullen 53300.00.00	20mg/1ml	Solution for injection	Injection
Germany	Germany Tad Pharma Gmbh Heinz-Lohmann-Str. 5 D-27472 Cuxhaven	Flexase S 29786.00.00	20mg	Suppository	Rectal use
Germany	Germany Tad Pharma Gmbh Heinz-Lohmann-Str. 5 D-27472 Cuxhaven	Flexase Uno 6691665.01.00	20mg	Tablet	Oral use
Germany	Germany Weimer Pharma Gmbh Im Steingerüst 30 D- 76437 Rastatt	Piroxicam Weimer Injektionslösung 20 Mg/MI 49635.00.00	20mg/1ml	Solution for injection	Injection
Germany	Germany Wieb Pharm Vertriebs Gmbh & Co.Kg Diestraat 15 D-25870 Norderfriedrichskoog	Pirowieb 20 Amp. 36620.00.00	20mg/1ml	Solution for injection	Injection
Germany	Germany Wieb Pharm Vertriebs Gmbh & Co.Kg Diestraat 15 D-25870 Norderfriedrichskoog	Pirowieb 20 Mg 12428.00.00	20mg	Tablet	Oral use
Germany	Germany Wieb Pharm Vertriebs Gmbh & Co.Kg Diestraat 15 D-25870 Norderfriedrichskoog	Pirowieb 20mg Inj.- Lsg. 53302.00.00	20mg/1ml	Solution for injection	Injection

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Germany	Germany Winthrop Arzneimittel Gmbh Industriestr. 10 D-82256 Fürstfeldbruck Germany	Piroflam 10 Mg 40937.00.00	10mg	Capsule	Oral use
Germany	Winthrop Arzneimittel Gmbh Industriestr. 10 D-82256 Fürstfeldbruck Germany	Piroflam 10 Mg Tabs Lichtenstein 6144727.00.00	10mg	Tablet	Oral use
Germany	Winthrop Arzneimittel Gmbh Industriestr. 10 D-82256 Fürstfeldbruck Germany	Piroflam 20mg Tabs Lichtenstein 6144727.01.00	20mg	Tablet	Oral use
Germany	Winthrop Arzneimittel Gmbh Industriestr. 10 D-82256 Fürstfeldbruck Germany	Piroflam Suppos Lichtenstein 6144779.00.00	20mg	Suppository	Rectal use
Denmark	Merck NM AB Ynglingagatan 14 11347, Post Box 23033 SE-10435 Stockholm Sweden	Piroxicam " Merck NM"	10 mg	Tablet	Oral use
Denmark	Merck NM AB Ynglingagatan 14 11347, Post Box 23033 SE-10435 Stockholm Sweden	Piroxicam "Merck NM"	20 mg	Tablet	Oral use
Denmark	Merck NM AB Ynglingagatan 14 11347, Post Box 23033 SE-10435 Stockholm	Piroxicam "Merck NM"	10 mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Denmark	Sweden Merck NM AB Ynglingagatan 14 11347, Post Box 23033 SE-10435 Stockholm	Piroxicam "Merck NM"	20 mg	Capsule	Oral use
Denmark	Sweden Pfizer Aps Lautrupvang 8 Dk-2750 Ballerup	Felden	20 mg	Dispersible Tablet	Oral use
Denmark	Denmark Pfizer Aps Lautrupvang 8 Dk-2750 Ballerup	Felden	0.5 %	Gel	Cutaneous use
Denmark	Denmark Sandoz A/S C.F. Tietgens Boulevard 40 DK-5220 Odense SØ	Pirom	10 mg	Tablet	Oral use
Denmark	Denmark Sandoz A/S C.F. Tietgens Boulevard 40 DK-5220 Odense SØ	Pirom	20 mg	Tablet	Oral use
Denmark	Denmark Hexal A/S Kanalholmen 8-12 Dk-2650 Hvidovre	Piroxigea	10 mg	Tablet	Oral use
Denmark	Denmark Hexal A/S Kanalholmen 8-12 Dk-2650 Hvidovre	Piroxigea	20 mg	Tablet	Oral use
Greece	Denmark DEMO ABEE 21st Km National Road	Oximezin	10 mg/tab	Gastro resistant tablet	Oral

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Greece	Athens-Lamia 14565 Greece DEMO ABEE 21st Km National Road Athens-Lamia 14565 Greece	Oximezin	20 mg/tab	Gastro resistant tablet	Oral
Greece	DEMO ABEE 21st Km National Road Athens-Lamia 14565 Greece	Oximezin	20 mg/1ml	Inj sol	Intramuscular
Greece	DEMO ABEE 21st Km National Road Athens-Lamia Post Code: 14565 Greece	Oximezin	0.50%	Gel	External
Greece	Pfizer Hellas Ae Mesogeion 243 New Psychiko 15451 Greece	Feldene	20 mg/sup	Suppository	Rectal
Greece	Pfizer Hellas Ae Mesogeion 243 New Psychiko 15451 Greece	Feldene	20 mg/tab	Dispersible tablet	Oral
Greece	Pfizer Hellas Ae Mesogeion 243 New Psychiko 15451 Greece	Feldene	10 mg/tab	Dispersible tablet	Oral
Greece	Pfizer Hellas Ae Mesogeion 243 New Psychiko 15451 Greece	Feldene	0.5%	Gel	External
Greece	Pfizer Hellas Ae Mesogeion 243	Feldene	20 mg/1ml	Inj sol	Intramuscular

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Greece	New Psychiko 15451 Greece Pfizer Hellas Ae Mesogeion 243 New Psychiko 15451 Greece	Feldene	10 mg/tab	Tabs rapid	Oral
Greece	Pfizer Hellas Ae Mesogeion 243 New Psychiko 15451 Greece	Feldene	20 mg/tab	Tabs rapid	Oral
Greece	Biomedica-Chemica G. Lyra 25, Kato Kifissia Greece	Valopon	10 mg/cap	Hard capsules	Oral
Greece	Biomedica-Chemica G. Lyra 25, Kato Kifissia Greece	Valopon	20 mg/cap	Hard capsules	Oral
Greece	Biomedica-Chemica G. Lyra 25, Kato Kifissia Greece	Valopon	0.5%	Gel	External
Greece	Biomedica-Chemica G. Lyra 25, Kato Kifissia Greece	Valopon	20 mg/1ml	Inj sol	Intramuscular
Greece	Remedina Gounari 25 & Areos Kamatero Attiki 13451 Greece	Flodeneu	20 mg/cap	Hard capsules	Oral
Greece	Pharmaceutical Industry Proel Ae E.G. Koronis Dilou 9	Zerospam	20 mg/cap	Hard capsules	Oral

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Greece	Peristeri 12134 Greece Pharmaceutical Industry Proel Ae E.G. Koronis Dilou 9	Zerospam	0.5%	Gel	External
Greece	Peristeri 12134 Greece Help Aebe Valaoritou 10	Proponol	20 mg/cap	Hard capsules	Oral
Greece	Metamorfofi Attiki 14452 Greece Help Aebe Valaoritou 10	Proponol	10 mg/cap	Hard capsules	Oral
Greece	Metamorfofi Attiki 14452 Greece Help Aebe Valaoritou 10	Proponol	20 mg/sup	Suppository	Rectal
Greece	Metamorfofi Attiki 14452 Greece Help Aebe Valaoritou 10	Proponol	0.5%	Gel	External
Greece	Metamorfofi Attiki 14452 Greece Rafarm Aebe Korinthou 12	Zitumex	20 mg/cap	Hard capsules	Oral
Greece	New Psychiko 15451 Greece Rafarm Aebe Korinthou 12	Zitumex	20 mg/sup	Suppository	Rectal
Greece	New Psychiko 15451 Greece Rafarm Aebe Korinthou 12	Zitumex	0.5%	Gel	External

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Greece	New Psychiko 15451 Greece Rafarm Aebe Korinthou 12 New Psychiko 15451 Greece	Zitumex	20 mg/1ml	Inj sol	Intramuscular
Greece	Vilco Ae Pefkon 121 Neo Irakleio 14122 Greece	Pedifan	20 mg/cap	Hard capsules	Oral
Greece	Vilco Ae Pefkon 121 Neo Irakleio 14122 Greece	Pedifan	0.5%	Gel	External
Greece	Faran Abee Achaias & Troizinias New Kifissia 14564 Greece	Calmopyrol	20 mg/cap	Hard capsules	Oral
Greece	Faran Abee Achaias & Troizinias New Kifissia 14564 Greece	Calmopyrol	20 mg/sup	Suppository	Rectal
Greece	MENTINOVA AE 16th Km Marathonos Avenue Pallini Attiki 15344 Greece	Conzila	20 mg/tab	Tabs	Oral
Greece	MENTINOVA AE 16th Km Marathonos Avenue Pallini Attiki 15344 Greece	Conzila	0.5%	Gel	External
Greece	GENEPHARM AE 18th Km Marathonos Avenue	Grecotens	20 mg/cap	Hard capsules	Oral

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Greece	Pallini Attiki 15351 Greece GENEPHARM AE 18th Km Marathonos Avenue Pallini Attiki 15351 Greece	GrecoTens	0.5%	Gel	External
Greece	Coup Oe Kouparoussos & Sia Agias Varvaras 53 Dafni 17235 Greece	Ruvamed	20 mg/cap	Hard capsules	Oral
Greece	Coup Oe Kouparoussos & Sia Agias Varvaras 53 Dafni 17235 Greece	Ruvamed	0.5%	Gel	External
Greece	Kleva Epe Parnithos Avenue 189 Acharnai Attiki 13671 Greece	Pyrcost	20 mg/cap	Hard capsules	Oral
Greece	Kleva Epe Parnithos Avenue 189 Acharnai Attiki 13671 Greece	Pyrcost	0.5%	Gel	External
Greece	Kleva Epe Parnithos Avenue 189 Acharnai Attiki 13671 Greece	Pyrcost	20 mg/sup	Suppository	Rectal
Greece	Kleva Epe Parnithos Avenue 189 Acharnai Attiki 13671 Greece	Pyrcost	20 mg/1ml	Inj sol	Intramuscular
Greece	Kleva Epe Parnithos Avenue 189	Felcam	10 mg/cap	Hard capsules	Oral

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Greece	Acharnai Attiki 13671 Greece Kleva Epe Parnithos Avenue 189 Acharnai Attiki 13671 Greece	Felcam	20 mg/cap	Hard capsules	Oral
Greece	Kleva Epe Parnithos Avenue 189 Acharnai Attiki 13671 Greece	Felcam	0.5%	Gel	External
Greece	Kleva Epe Parnithos Avenue 189 Acharnai Attiki 13671 Greece	Felcam	20 mg/sup	Suppository	Rectal
Greece	Viostam K. Mpougias & Sia E.E. Padiamantopoulou 66 Zografou 157 71 Athens	Painrelipt-D	0.5%	Gel	External
Greece	Norma Hellas Ae Menandrou 54 Athens 10431 Greece	Neo Axedil	20 mg/cap	Hard capsules	Oral
Greece	Norma Hellas Ae Menandrou 54 Athens 10431 Greece	Neo Axedil	20 mg/1ml	Inj sol	Intramuscular
Greece	Anfarm Hellas Ae K. Palaiologou & Perikleous 27 Chalandri 15232 Greece	Bleduran	20 mg/cap	Hard capsules	Oral
Greece	Anfarm Hellas Ae K. Palaiologou & Perikleous 27	Bleduran	0.5%	Gel	External

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Greece	Chalandri 15232 Greece Gap Ae Agisilaou 46 Agios Dimitrios 17341 Greece	Piroxicam/Gap	20 mg/cap	Hard capsules	Oral
Greece	Gap Ae Agisilaou 46 Agios Dimitrios 17341 Greece	Piroxicam/Gap	10 mg/cap	Hard capsules	Oral
Greece	Chiesi Hellas Aebe Anapafseos Avenue 30 Vrilissia 15235 Greece	Brexin	20 mg/sachet	Grannules for oral solution	Oral
Greece	Chiesi Hellas Aebe Anapafseos Avenue 30 Vrilissia 15235 Greece	Brexin	20 mg/tab	Tablets	Oral
Greece	Chiesi Hellas Aebe Anapafseos Avenue 30 Vrilissia 15235 Greece	Brexin	20 mg/tab	Effervescent tablets	Oral
Greece	Pharmanel Pharmaceutical Ae Marathonos 106 Gerakas 15344 Greece	Sinartrol	15 mg/tab	Tablets	Oral
Greece	Pharmanel Pharmaceutical Ae Marathonos 106 Gerakas 15344 Greece	Sinartrol	1.5%	Cream	External
Greece	Pharmanel Pharmaceutical Ae Marathonos 106	Sinartrol	30 mg/tab	Tablets	Oral

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	Gerakas 15344 Greece				
Spain	Nefox Farma S.A. Avda. De Europa, 20 B 28108 Alcobendas Madrid Spain	Feldene	10 mg	Capsule, hard	Oral use
Spain	Nefox Farma S.A. Avda. De Europa, 20 B 28108 Alcobendas Madrid Spain	Feldene	20 mg	Capsule, hard	Oral use
Spain	Nefox Farma S.A. Avda. De Europa, 20 B 28108 Alcobendas Madrid Spain	Feldene	20 mg	Suppository	Rectal use
Spain	Nefox Farma S.A. Avda. De Europa, 20 B 28108 Alcobendas Madrid Spain	Feldene	20mg/ml	Solution for injection	Parenteral use
Spain	Nefox Farma S.A. Avda. De Europa, 20 B 28108 Alcobendas Madrid Spain	Feldene	20 mg	Dispersible tablet	Oral use
Spain	Nefox Farma S.A. Avda. De Europa, 20 B 28108 Alcobendas Madrid Spain	Feldene Flas	20 mg	Liophilised	Oral use
Spain	Nefox Farma S.A. Avda. De Europa, 20 B 28108 Alcobendas Madrid Spain	Feldegel	10-60 g	Gel	Cutaneous use
Spain	Chiesi España, S.A. Av. Berlin, 38-48 7ª Planta	Brexinil	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Spain	08029 Barcelona Spain Chiesi España, S.A. Av. Berlin, 38-48 7ª Planta 08029 Barcelona	Brexinil	20 mg	Effervescent tablet	Oral use
Spain	Spain Chiesi España, S.A. Av. Berlin, 38-48 7ª Planta 08029 Barcelona	Brexinil Sobres	20 mg	Powder for oral solution	Oral use
Spain	Spain Chiesi España, S.A. Av. Berlin, 38-48 7ª Planta 08029 Barcelona	Cycladol	20 mg	Tablet	Oral use
Spain	Spain Chiesi España, S.A. Av. Berlin, 38-48 7ª Planta 08029 Barcelona	Cycladol Dref	20 mg	Effervescent tablet	Oral use
Spain	Spain Chiesi España, S.A. Av. Berlin, 38-48 7ª Planta 08029 Barcelona	Cycladol	20 mg	Powder for oral solution	Oral use
Spain	Spain Quimifar, S.A. Comadran 37 Barbera Del Valles 08210 Barcelona	Doblexan	20 mg	Suppository	Rectal use
Spain	Spain Quimifar, S.A. Comadran 37 Barbera Del Valles 08210 Barcelona	Doblexan	10 mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Spain	Quimifar, S.A. Comadran 37 Barbera Del Valles 08210 Barcelona Spain	Doblexan	20 mg	Capsule	Oral use
Spain	Rottapharm, S.L. Carretera De Barcelona 2 46132 Almacera Spain	Improntal	10 mg	Capsule	Oral use
Spain	Rottapharm, S.L. Carretera De Barcelona 2 46132 Almacera Spain	Improntal	20 mg	Capsule	Oral use
Spain	Rottapharm, S.L. Carretera De Barcelona 2 46132 Almacera Spain	Improntal	20 mg	Dispersible tablet	Oral use
Spain	Rottapharm, S.L. Carretera De Barcelona 2 46132 Almacera Spain	Improntal	5mg/g	Cream	Cutaneous use
Spain	Rottapharm, S.L. Carretera De Barcelona 2 46132 Almacera Spain	Improntal	20mg/ml	Suppository	Rectal use
Spain	Laboratorios Cinfa, S.A. Olaz-Chipi, 10. Polig. Areta 31620 Huarte Pamplona Spain	Piroxicam Cinfa	20 mg	Dispersible tablet	Oral use
Spain	Laboratorios Edigen, S.A Chile 8, 2º Oficina 203. Edificio Euromadrid	Piroxicam Edigen	20 mg	Dispersible tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Spain	Las Matas 28290 Madrid Spain Pharmagenus ,S.A Passeig De Gracia, 55 5º 1ª. 08007 Barcelona Spain	Piroxicam Pharmagenus	20 mg	Dispersible tablet	Oral use
Spain	Ratiopharm España, S.A. Avda. De Burgos 16 D - 5ª Planta 28036 Madrid Spain	Piroxicam Ratiopharm	20 mg	Capsule	Oral use
Spain	Ratiopharm España, S.A. Avda. De Burgos 16 D - 5ª Planta 28036 Madrid Spain	Piroxicam Ratiopharm	20 mg	Suppository	Rectal use
Spain	Laboratorios Salvat S.A.Gallo, 30-36 08950 Barcelona Spain	Salvacam	20 mg	Capsule	Oral use
Spain	Laboratorios Salvat S.A.Gallo, 30-36 08950 Barcelona Spain	Salvacam	0.50%	Gel	Cutaneous use
Spain	Laboratorios faes Farma Sa maximo Aguirre, 14 48940 Lamiaco-Lejona Spain	Sasulen	20 mg	Capsule	Oral use
Spain	Laboratorios Faes Farma Sa Maximo Aguirre, 14 48940 Lamiaco-Lejona Spain	Sasulen	20 mg	Dispersible tablet	Oral use
Spain	Laboratorios Faes Farma Sa	Sasulen	0.50%	Gel	Cutaneous use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Spain	Maximo Aguirre, 14 48940 Lamiaco-Lejona Spain Laboratorios Faes Farma Sa Maximo Aguirre, 14 48940 Lamiaco-Lejona Spain	Sasulen	20 mg	Suppository	Rectal use
Spain	Laboratorios Robert, S.A. Gran Via Carlos Iii 94 08028 Barcelona Spain	Vitaxicam	20 mg	Capsule	Oral use
Spain	Laboratorios Robert, S.A. Gran Via Carlos Iii 94 08028 Barcelona Spain	Vitaxicam	20 mg	Suppository	Rectal use
Spain	Laboratorios Robert, S.A. Gran Via Carlos Iii 94 08028 Barcelona Spain	Vitaxicam Topico	0.50%	Gel	Cutaneous use
Spain	Laboratorios Robert, S.A. Gran Via Carlos Iii 94 08028 Barcelona Spain	Vitaxicam	10 mg	Tablet	Oral use
Estonia	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexin	20mg	Tablet	Oral use
Estonia	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexin	20mg	Powder for oral solution	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Estonia	Pfizer Europe Ma Eeig Ramsgate Road Sandwich Kent Ct13 9nj United Kingdom	Feldene	0.5 %	Gel	Transdermal use
Finland	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexidol	20 mg	Tablet	Oral use
Finland	Pfizer Oy Tietokuja 3 00330 Helsinki Finland	Felden	0.5 %	Gel	Cutaneous use
Finland	Pfizer Oy Tietokuja 3 00330 Helsinki Finland	Felden	20 mg	Capsule, hard	Oral use
Finland	Pfizer Oy Tietokuja 3 00330 Helsinki Finland	Felden	20 mg	Tablet	Oral use
Finland	Alpharma A/S Harbitzalleen 3 158 Skoyen 0212 Oslo Norway	Piroxal	20 mg	Tablet	Oral use
Finland	Merckle Gmbh Ludwig-Merckle-Strasse 3 P.O. Box 1161 89143 Blaubeuren Germany	Piroxin	0.5 %	Gel	Cutaneous use
France	Ajc Pharma	Zofora 20 Mg,	20 mg	Suppository	Rectal use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	18, Rue Du Docteur Ragnaud 16000 Angoulême France	Suppositoire			
France	Biogaran 15, Boulevard Charles De Gaulle 92707 Colombes Cedex France	Piroxicam Biogaran 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Biogaran 15, Boulevard Charles De Gaulle 92707 Colombes Cedex France	Piroxicam Biogaran 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Laboratoire Pharmy II 26 rue des Gaudines 78100 Saint-Germain-Laye France	Zofora 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Laboratoire Pharmy II 26 rue des Gaudines 78100 Saint-Germain-Laye France	Zofora 20 Mg/1 Ml, Solution Injectable (I.M.)	20 mg	Solution for injection	Intramuscular use
France	Laboratoire Pharmy II 26 rue des Gaudines 78100 Saint-Germain-Laye France	Zofora 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Cephalon France 20, Rue Charles Martigny 94701 Maisons-Alfort Cedex France	Proxalyoc 20 Mg, Lyophilisat Oral	20 mg	Lyophilisat	Oral use
France	Cephalon France 20, Rue Charles Martigny 94701 Maisons-Alfort Cedex France	Proxalyoc 10 Mg, Lyophilisat Oral	10 mg	Lyophilisat	Oral use
France	Chiesi	Cycladol 20 Mg,	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	11, Avenue Dubonnet 92400 Courbevoie France	Comprimé Effervescent			
France	Chiesi 11, Avenue Dubonnet 92400 Courbevoie France	Cycladol 20 Mg, Poudre Pour Suspension Buvable En Sachet	20 mg	Powder	Oral use
France	Chiesi 11, Avenue Dubonnet 92400 Courbevoie France	Cycladol 20 Mg, Comprimé Sécable	20 mg	Tablet	Oral use
France	Chiesi 11, Avenue Dubonnet 92400 Courbevoie France	Cycladol 20 Mg, Suppositoire	20 mg	Suppository	Rectal use
France	Dexo 179, Bureaux De La Colline 92213 Saint-Cloud Cedex France	Inflaced 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Dexo 179, Bureaux De La Colline 92213 Saint-Cloud Cedex France	Inflaced 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Dexo 179, Bureaux De La Colline 92213 Saint-Cloud Cedex France	Inflaced 20 Mg, Poudre Effervescente En Sachet	20 mg	Powder	Oral use
France	Eg Labo - Laboratoires Eurogenerics "Le Quintet" - Bâtiment A 12, Rue Danjou 92517 Boulogne Billancourt Cedex France	Piroxicam Eg 20 Mg, Gélule	20 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
France	Eg Labo - Laboratoires Eurogenerics "Le Quintet" - Bâtiment A 12, Rue Danjou 92517 Boulogne Billancourt Cedex France	Piroxicam Eg 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Expanpharm International 6, rue de la Rochefoucauld 16000 Angouleme France	Piroxicam Expanpharm 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Expanpharm International 6, rue de la Rochefoucauld 16000 Angouleme France	Piroxicam Expanpharm 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Laboratories Fournier S.A. 28, Boulevard Clemenceau 21000 Dijon France	Piroxicam Fournier 20 Mg/ML, Solution Injectable (Im)	20 mg	Solution for injection	Intramuscular use
France	Innotech International 7-9, Avenue François-Vincent Raspail Bp 32, 94111 Arcueil Cedex France	Pirotec 20 Mg/1 ML, Solution Injectable	20 mg	Solution for injection	Intramuscular use
France	Innotech International 7-9, Avenue François-Vincent Raspail Bp 32, 94111 Arcueil Cedex France	Piroxicam Innotech International 20 Mg/1 ML, Solution Injectable	20 mg	Solution for injection	Intramuscular use
France	Innotech International 7-9, Avenue François-Vincent Raspail Bp 32, 94111 Arcueil Cedex France	Piroxicam Innotech International 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Innotech International 7-9, Avenue François-Vincent Raspail Bp 32, 94111 Arcueil Cedex France	Piroxicam Innotech International 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Innotech International	Pirotec 20 Mg,	20 mg	Suppository	Rectal use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	7-9, Avenue François-Vincent Raspail Bp 32, 94111 Arcueil Cedex France	Suppositoire			
France	Innotech International 7-9, Avenue François-Vincent Raspail Bp 32, 94111 Arcueil Cedex France	Piroxicam Innothera 20 Mg, Suppositoire	20 mg	Suppository	Rectal use
France	Ivax Pharmaceuticals 34, Avenue Franklin Roosevelt 92150 Suresnes France	Piroxicam Ivax 20 Mg/1 Ml, Solution Injectable (Im)	20 mg	Solution for injection	Intramuscular use
France	Ivax Pharmaceuticals 34, Avenue Franklin Roosevelt 92150 Suresnes France	Piroxicam Ivax 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Ivax Pharmaceuticals 34, Avenue Franklin Roosevelt 92150 Suresnes France	Piroxicam Ivax 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Ivax Pharmaceuticals 34, Avenue Franklin Roosevelt 92150 Suresnes France	Piroxicam Ivax 20 Mg, Suppositoire	20 mg	Suppository	Rectal use
France	Laboratoire Rpg - Ranbaxy Pharmacie Generiques 4, Place Louis Armand, 75012 Paris France	Piroxicam Rpg 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Laboratoire Rpg - Ranbaxy Pharmacie Generiques 4, Place Louis Armand, 75012 Paris France	Piroxicam Rpg 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Merck Generiques	Piroxicam Merck 10	10 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	34, Rue Saint-Romain, 69359 Lyon Cedex 08 France	Mg, Gélule			
France	Merck Generiques 34, Rue Saint-Romain, 69359 Lyon Cedex 08 France	Piroxicam Merck 20 Mg/1 ML, Solution Injectable (Im)	20 mg	Solution for injection	Intramuscular use
France	Merck Generiques 34, Rue Saint-Romain, 69359 Lyon Cedex 08 France	Piroxicam Merck 20 Mg, Comprimé Dispersible Sécable	20 mg	Tablet	Oral use
France	Merck Generiques 34, Rue Saint-Romain, 69359 Lyon Cedex 08 France	Piroxicam Merck 20 Mg, Suppositoire	20 mg	Suppository	Rectal use
France	Merck Generiques 34, Rue Saint-Romain, 69359 Lyon Cedex 08 France	Piroxicam Merck 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Palbian Eurasanté - Parc Galénis, 85 C Rue Nelson Mandela 59120 Loos France	Piroxicam Palbian 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Palbian Eurasanté - Parc Galénis, 85 C Rue Nelson Mandela 59120 Loos France	Piroxicam Palbian 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Pfizer 23-25, Avenue Du Docteur Lannelongue 75668 Paris Cedex 14	Feldene 10 Mg, Gélule	10 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
France	France Pfizer 23-25, Avenue Du Docteur Lannelongue 75668 Paris Cedex 14	Feldene 20 Mg/1 Ml, Solution Injectable En Ampoule (Im)	20 mg	Solution for injection	Intramuscular use
France	France Pfizer 23-25, Avenue Du Docteur Lannelongue 75668 Paris Cedex 14	Feldene 20 Mg, Suppositoire	20 mg	Suppository	Rectal use
France	France Pfizer 23-25, Avenue Du Docteur Lannelongue 75668 Paris Cedex 14	Feldene Dispersible 20 Mg, Comprimé Sécable	20 mg	Tablet	Oral use
France	France Pfizer 23-25, Avenue Du Docteur Lannelongue 75668 Paris Cedex 14	Feldene 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	France Pfizer 23-25, Avenue Du Docteur Lannelongue 75668 Paris Cedex 14	Geldene 0,5 Pour Cent, Gel Pour Application Locale	0,500 g	Gel	Cutaneous use
France	France Pfizer Holding France 23-25, Avenue Du Docteur Lannelongue 75014 Paris	Piroxicam Beral 20 Mg, Suppositoire	20 mg	Suppository	Rectal use
France	France Pfizer Holding France 23-25, Avenue Du Docteur Lannelongue 75014 Paris	Piroxicam Beral 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	France Pfizer Holding France 23-25, Avenue Du Docteur Lannelongue 75014 Paris	Piroxicam Beral Dispersible 20 Mg, Comprimé	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
France	France Pfizer Holding France 23-25, Avenue Du Docteur Lannelongue 75014 Paris	Dispersible Sécable Piroxicam Beral 20 Mg/1 Ml, Solution Injectable En Ampoule (Im)	20 mg	Solution for injection	Intramuscular use
France	France Pfizer Holding France 23-25, Avenue Du Docteur Lannelongue 75014 Paris	Piroxicam Beral 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	France Pfizer Holding France 23-25, Avenue Du Docteur Lannelongue 75014 Paris	Piroxicam Beral 0,5 Pour Cent, Gel	0,5 g	Gel	Cutaneous use
France	France Pierre Fabre Medicament 45, Place Abel Gance 92654 Boulogne Cedex	Brexin 20 Mg, Poudre Pour Suspension Buvable	20 mg	Powder	Oral use
France	France Pierre Fabre Medicament 45, Place Abel Gance 92654 Boulogne Cedex	Brexin 20 Mg, Suppositoire	20 mg	Suppository	Rectal use
France	France Pierre Fabre Medicament 45, Place Abel Gance 92654 Boulogne Cedex	Brexin 20 Mg, Comprimé Effervescent	20 mg	Tablet	Oral use
France	France Pierre Fabre Medicament 45, Place Abel Gance 92654 Boulogne Cedex	Brexin 20 Mg, Comprimé Sécable	20 mg	Tablet	Oral use
France	France Ratiopharm 5, Rue Charles Martigny, Bp 42, 94702 Maisons-Alfort Cedex	Piroxicam- Ratiopharm 20 Mg, Gélule	20 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
France	France Sandoz 49, Avenue Georges Pompidou 92300 Levallois-Perret	Piroxicam Sandoz 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	France Sandoz 49, Avenue Georges Pompidou 92300 Levallois-Perret	Piroxicam Gnr 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	France Teva Classics Le Palatin 1, 1, Cours Du Triangle, 92936 Paris La Défense Cedex	Piroxicam Teva 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	France Teva Classics Le Palatin 1, 1, Cours Du Triangle, 92936 Paris La Défense Cedex	Piroxicam Teva 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	France Teva Classics Le Palatin 1, 1, Cours Du Triangle, 92936 Paris La Défense Cedex	Piroxicam Teva 20 Mg/1 ML, Solution Injectable (Im)	20 mg	Solution for injection	Intramuscular use
France	France Teva Pharma Bv Industrieweg 23 Po Box 217, 3640 Ae Mijdrecht The Netherlands	Piroxicam Teva Pharma 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	France Teva Pharma Bv Industrieweg 23 Po Box 217,	Piroxicam Teva Pharma 10 Mg, Gélule	10 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
France	3640 Ae Mijdrecht The Netherlands Meda Pharma 25, Boulevard de l'Amiral Bruix 75016 Paris France	Flexirox 20 Mg/MI, Solution Injectable (Im)	20 mg	Solution for injection	Intramuscular use
France	Meda Pharma 25, Boulevard de l'Amiral Bruix 75016 Paris France	Flexirox 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Meda Pharma 25, Boulevard de l'Amiral Bruix 75016 Paris France	Flexirox 20 Mg, Poudre Effervescente En Sachet-Dose	20 mg	Powder	Oral use
France	Meda Pharma 25, Boulevard de l'Amiral Bruix 75016 Paris France	Flexirox 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Meda Pharma 25, Boulevard de l'Amiral Bruix 75016 Paris France	Flexirox 2 Mg/MI, Suspension Buvable En Flacon	200 mg	Suspension	Oral use
France	Winthrop Medicaments 1/13, Boulevard Romain Rolland 75014 Paris France	Piroxicam Winthrop 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Winthrop Medicaments 1/13, Boulevard Romain Rolland 75014 Paris France	Piroxicam Winthrop 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
France	Winthrop Medicaments 1/13, Boulevard Romain Rolland	Olcam 10 Mg, Gélule	10 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
France	75014 Paris France Winthrop Medicaments 1/13, Boulevard Romain Rolland 75014 Paris France	Olcam 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Zydus France 25, Rue Des Peupliers, Zac Les Hautes Pâtures - Parc D'activités Des Peupliers, 92000 Nanterre France	Piroxicam Zydus 20 Mg, Gélule	20 mg	Capsule, hard	Oral use
France	Zydus France 25, Rue Des Peupliers, Zac Les Hautes Pâtures - Parc D'activités Des Peupliers, 92000 Nanterre France	Piroxicam Zydus 10 Mg, Gélule	10 mg	Capsule, hard	Oral use
Hungary	Aliud Pharma Gmbh &Co. Kg. Gottlieb-Daimler Str. 19 89150 Laichingen Germany	Piroxicam Al	10mg	Tablet	Oral use
Hungary	Aliud Pharma Gmbh &Co. Kg. Gottlieb-Daimler Str. 19 89150 Laichingen Germany	Piroxicam Al	20mg	Tablet	Oral use
Hungary	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Flamexin	20mg	Tablet	Oral use
Hungary	Torrex Chiesi Pharma Gmbh Gonzagagasse 16/16 1010 Vienna Austria	Brexin	20mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Hungary	Egis Gyógyszergyár Nyrt. Keresztúri U. 30-38 1106 Budapest Hungary	Hotemin	10mg	Suppository	Rectal use
Hungary	Egis Gyógyszergyár Nyrt. Keresztúri U. 30-38 1106 Budapest Hungary	Hotemin	20mg	Suppository	Rectal use
Hungary	Egis Gyógyszergyár Nyrt. Keresztúri U. 30-38 1106 Budapest Hungary	Hotemin	10mg	Capsule	Oral use
Hungary	Egis Gyógyszergyár Nyrt. Keresztúri U. 30-38 1106 Budapest Hungary	Hotemin	20mg	Capsule	Oral use
Hungary	Egis Gyógyszergyár Nyrt. Keresztúri U. 30-38 1106 Budapest Hungary	Hotemin	10m/1g	Cream	Topical use
Hungary	Sandoz Hungaria Kft. 1034 Budapest, Tímár U. 8. Hungary	Pirorheum	20mg	Tablet	Oral use
Hungary	Sandoz Hungaria Kft. 1034 Budapest, Tímár U. 8. Hungary	Pirorheum	20mg	Injection	Parenteral use
Hungary	Pfizer Kft. Thurzó U. 5/C 1133 Budapest Hungary	Feldene	10mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Hungary	Pfizer Kft. Thurzó U. 5/C 1133 Budapest Hungary	Feldene Dispersal	20mg	Tablet	Oral use
Hungary	Pfizer Kft. Thurzó U. 5/C 1133 Budapest Hungary	Feldene Flash	20mg	Tablet	Sublingual use
Hungary	Biogal-Teva Pharma Rákóczi U. 70-72 1074 Budapest Hungary	Piroxicam-B	20mg	Capsule	Oral use
Hungary	Biogal-Teva Pharma Rákóczi U. 70-72 1074 Budapest Hungary	Piroxicam-B	10mg	Capsule	Oral use
Hungary	Teva Gyógyszergyár Zrt. Pallagi U. 13 4042 Debrecen Hungary	Huma-Pirocam	20mg	Capsule	Oral use
Hungary	Teva Gyógyszergyár Zrt. Pallagi U. 13 4042 Debrecen Hungary	Huma-Pirocam	10mg	Capsule	Oral use
Hungary	Slovakofarma As Nitrianská 100 92027 Hlomovec Hungary	Reumador	5mg/1g	Gel	Transdermal use
Ireland	Trinity Chiesi Pharmaceuticals Ltd Cheadle Royal Business Park Highfield, Cheadle Sk8 3gy United Kingdom	Brexidol 20mg Tablets	20mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Ireland	Trinity Chiesi Pharmaceuticals Ltd Cheadle Royal Business Park Highfield, Cheadle Sk8 3gy United Kingdom	Brexidol 20mg Effervescent Tablets	20mg	Tablet	Oral use
Ireland	Pfizer Limited Walton Oaks, Dorking Road Walton-0n-The-Hill Surrey KT20 7NS United Kingdom	Feldene 10 Mg Capsules	10mg	Capsule, hard	Oral use
Ireland	Pfizer Limited Walton Oaks, Dorking Road Walton-0n-The-Hill Surrey KT20 7NS United Kingdom	Feldene 20mg Capsules	20mg	Capsule, hard	Oral use
Ireland	Pfizer Limited Walton Oaks, Dorking Road Walton-0n-The-Hill Surrey KT20 7NS United Kingdom	Feldene Suppositories 20mg	20mg	Suppository	Rectal use
Ireland	Pfizer Limited Walton Oaks, Dorking Road Walton-0n-The-Hill Surrey KT20 7NS United Kingdom	Feldene Gel 0.5%	0.50%	Gel	Topical use
Ireland	Pfizer Healthcare Ireland 9 Riverwalk National Digital Park Citywest Business Campus Dublin 24 Ireland	Feldene Topigel		Gel	Topical use
Iceland	Pfizer Aps Lautrupvang 8	Felden	20 mg	Dispersible tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Iceland	Dk 2750 Ballerup Denmark Pfizer Aps Lautrupvang 8 Dk 2750 Ballerup Denmark	Felden Gel	0.5 %	Gel	Topical use
Italy	Abc Farmaceutici S.P.A. Corso Vittorio Emanuele Ii, 72 10121 Torino Italy	Piroxicam Abc	20 mg	Capsule, hard	Oral use
Italy	Abc Farmaceutici S.P.A. Corso Vittorio Emanuele Ii, 72 10121 Torino Italy	Piroxicam Abc	20 mg	Suppository	Rectal use
Italy	Abc Farmaceutici S.P.A. Corso Vittorio Emanuele Ii, 72 10121 Torino Italy	Piroxicam Abc	1%	Gel	Cutaneous use
Italy	Aesculapius Farmaceutici Srl Via Cozzaglio, 24 25125 Brescia Italy	Clevian	1%	Gel	Cutaneous use
Italy	Bioprogress S.P.A. Via Aurelia, 58 00165 Roma Italy	Oxicam	20 mg	Capsule, hard	Oral use
Italy	Bioprogress S.P.A. Via Aurelia, 58 00165 Roma Italy	Oxicam	1%	Gel	Cutaneous use
Italy	Bruschettini S.R.L. Via Isonzo, 6	Bruxicam	20 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	16147 Genova Italy Bruschettini S.R.L. Via Isonzo, 6 16147 Genova Italy	Bruxicam	20 mg	Suppository	Rectal use
Italy	16147 Genova Italy Bruschettini S.R.L. Via Isonzo, 6 16147 Genova Italy	Bruxicam	1%	Cream	Cutaneous use
Italy	16147 Genova Italy Bruschettini S.R.L. Via Isonzo, 6 16147 Genova Italy	Piroftal	0,5%	Eye drops, solution	Ocular use
Italy	Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexidol	20 mg	Tablet	Oral use
Italy	Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexidol	20 mg	Effervescent Tablet	Oral use
Italy	Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexidol	20 mg	Granules for oral solution	Oral use
Italy	Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexidol	20 mg	Suppository	Rectal use
Italy	Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A	Brexin L	20 mg/2 ml	Powder and solvent for solution for injection	Intramuscular use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	43100 Parma Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma	Pivaloxicam	30 mg	Capsule, hard	Oral use
Italy	43100 Parma Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma	Pivaloxicam	2%	Cream	Cutaneous use
Italy	43100 Parma Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma	Pivaloxicam	30 mg	Capsule, hard	Oral use
Italy	43100 Parma Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma	Pivaloxicam	50 g	Cream	Cutaneous use
Italy	43100 Parma Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma	Pivaloxicam	40 g	Cream	Cutaneous use
Italy	43100 Parma Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma	Pivaloxicam	30 g	Cream	Cutaneous use
Italy	Italy Copernico S.R.L. Via Oria, 32 72028 Torre Santa Susanna (Br)	Euroxi	20 mg	Capsule, hard	Oral use
Italy	Italy Copernico S.R.L. Via Oria, 32	Euroxi	50 g	Gel	Cutaneous use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	72028 Torre Santa Susanna (Br) Italy Copernico S.R.L. Via Oria, 32 72028 Torre Santa Susanna (Br) Italy	Spirox	20 mg/1 ml	Solution for injection	Intramuscular use
Italy	Doc Generici Srl Via Manuzio, 7 20124 Milano Italy	Piroxicam Doc	20 mg	Capsule, hard	Oral use
Italy	Doc Generici Srl Via Manuzio, 7 20124 Milano Italy	Piroxicam Doc	1%	Cream	Cutaneous use
Italy	Doc Generici Srl Via Manuzio, 7 20124 Milano Italy	Piroxicam Doc	20 mg/ml	Solution for injection	Intramuscular use
Italy	Doc Generici Srl Via Manuzio, 7 20124 Milano Italy	Piroxicam Doc Generici	20 mg	Capsule, hard	Oral use
Italy	Dorom S.R.L. Viale G. Richard, 7 20143 Milano Italy	Piroxicam	10 mg	Capsule, hard	Oral use
Italy	Dorom S.R.L. Viale G. Richard, 7 20143 Milano Italy	Piroxicam	20 mg	Suppository	Rectal use
Italy	Eg S.P.A. Via Scarlatti Domenico, 31	Piroxicam Eg	20 mg/ml	Solution for injection	Intramuscular use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	20124 Milano Italy Eg S.P.A. Via Scarlatti Domenico, 31 20124 Milano	Piroxicam Eg	20 mg	Capsule, hard	Oral use
Italy	20124 Milano Italy Eg S.P.A. Via Scarlatti Domenico, 31 20124 Milano	Piroxicam Eg	20 mg	Soluble Tablet	Oral use
Italy	Italy Epifarma S.R.L Via S.Rocco, 6 85033 Episcopia Pz	Ipsoflog	20 mg	Capsule, hard	Oral use
Italy	Italy Epifarma S.R.L Via S.Rocco, 6 85033 Episcopia Pz	Ipsoflog	1%	Cream	Cutaneous use
Italy	Italy Epifarma S.R.L Via S.Rocco, 6 85033 Episcopia Pz	Ipsoflog	20 mg/ 1 ml	Solution for injection	Intramuscular use
Italy	Italy Epifarma S.R.L Via S.Rocco, 6 85033 Episcopia Pz	Ipsoflog	20 mg	Soluble Tablet	Oral use
Italy	Italy F.I.R.M.A. S.P.A. Via Di Scandicci, 37 50143 Firenze	Antiflog	10 mg	Capsule, soft	Oral use
Italy	Italy F.I.R.M.A. S.P.A. Via Di Scandicci, 37	Antiflog	20 mg	Capsule, soft	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	50143 Firenze Italy F.I.R.M.A. S.P.A. Via Di Scandicci, 37 50143 Firenze	Antiflog	20 mg	Suppository	Rectal use
Italy	50143 Firenze Italy F.I.R.M.A. S.P.A. Via Di Scandicci, 37 50143 Firenze	Antiflog	1%	Gel	Cutaneous use
Italy	Italy Farma 1 S.R.L. Via Privata Maria Teresa, 11 20123 Milano	Flodol	20 mg	Capsule, hard	Oral use
Italy	Italy Farma 1 S.R.L. Via Privata Maria Teresa, 11 20123 Milano	Flodol	1%	Gel	Cutaneous use
Italy	Italy Farmaceutici Caber S.P.A. Viale Citta' D'europa, 681 00100 Roma	Roxenil	1%	Cream	Cutaneous use
Italy	Italy Farmaceutici Caber S.P.A. Viale Citta' D'europa, 681 00100 Roma	Roxenil	20 mg	Capsule, hard	Oral use
Italy	Italy Hexal S.P.A. Centro Direzionale Colleoni Palazzo Andromeda Via Paracelso, 16 20041 Agrate Brianza (Mi)	Piroxicam Hexal	10 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>		<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	Hexal S.P.A. Centro Direzionale Colleoni Palazzo Andromeda Via Paracelso, 16 20041 Agrate Brianza (Mi) Italy		Piroxicam Hexal	20 mg	Tablet	Oral use
Italy	Hexal S.P.A. Centro Direzionale Colleoni Palazzo Andromeda Via Paracelso, 16 20041 Agrate Brianza (Mi) Italy		Piroxicam Hexal	20 mg	Solution for injection	Intramuscular use
Italy	Jet Generici S.R.L. Via Mario Lalli, 8 56127 Pisa Italy		Piroxicam	20 mg	Capsule, hard	Oral use
Italy	K.B.R. Kroton Biologic Researches S.R.L. V.Emanuele, 73 88074 Crotona (Kr) Italy	Corso	Reumagil	1%	Cream	Cutaneous use
Italy	K.B.R. Kroton Biologic Researches S.R.L. V.Emanuele, 73 88074 Crotona (Kr) Italy	Corso	Reumagil	20 mg/1 ml	Solution for injection	Intramuscular use
Italy	Laboratori Alter S.R.L. Via Egadi, 7 20144 Milano Italy		Piroxicam Alter	20 mg/1 ml	Solution for injection	Intramuscular use
Italy	Laboratori Prodotti Farmaceutici Boniscontro E Gazzone S.R.L. Via Pavia, 6 20136 Milano		Roxiden	20 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	Italy Laboratori Prodotti Farmaceutici Boniscontro E Gazzone S.R.L. Via Pavia, 6 20136 Milano	Roxiden	20 mg	Suppository	Rectal use
Italy	Italy Laboratori Prodotti Farmaceutici Boniscontro E Gazzone S.R.L. Via Pavia, 6 20136 Milano	Roxiden	1%	Gel	Cutaneous use
Italy	Italy Laboratori Prodotti Farmaceutici Boniscontro E Gazzone S.R.L. Via Pavia, 6 20136 Milano	Roxiden	20 mg	Solution for injection	Intramuscular use
Italy	Italy Laboratorio Farmaceutico C.T. S.R.L. Strada Solaro, 75/77 18038 Villa Sayonara – Sanremo (Im)	Reucam	10 mg	Capsule, hard	Oral use
Italy	Italy Laboratorio Farmaceutico C.T. S.R.L. Strada Solaro, 75/77 18038 Villa Sayonara – Sanremo (Im)	Reucam	20 mg	Capsule, hard	Oral use
Italy	Italy Laboratorio Farmaceutico C.T. S.R.L. Strada Solaro, 75/77 18038 Villa Sayonara – Sanremo (Im)	Reucam	20 mg	Suppository	Rectal use
Italy	Italy Laboratorio Farmaceutico C.T. S.R.L. Strada Solaro, 75/77 18038 Villa Sayonara – Sanremo (Im)	Reucam	1%	Cream	Cutaneous use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	Lampugnani Farmaceutici Spa Bianca Maria Visconti, 33 20100 Milano Italy	Lampoflex	1%	Cream	Cutaneous use
Italy	Lampugnani Farmaceutici Spa Bianca Maria Visconti, 33 20100 Milano Italy	Lampoflex	20 mg	Capsule, hard	Oral use
Italy	Lampugnani Farmaceutici Spa Bianca Maria Visconti, 33 20100 Milano Italy	Lampoflex	1%	Cutaneous foam	Cutaneous use
Italy	Master Pharma S.R.L. Via Giacomo Chiesi 43100 Parma Italy	Cicladol	20 mg	Granules for oral solution	Oral use
Italy	Master Pharma S.R.L. Via Giacomo Chiesi 43100 Parma Italy	Cicladol	20 mg	Suppository	Rectal use
Italy	Master Pharma S.R.L. Via Giacomo Chiesi 43100 Parma Italy	Cicladol	20 mg	Tablet	Oral use
Italy	Master Pharma S.R.L. Via Giacomo Chiesi 43100 Parma Italy	Cicladol	20 mg	Effervescent Tablet	Oral use
Italy	Master Pharma S.R.L. Via Giacomo Chiesi 43100 Parma Italy	Ciclafast	30 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	Master Pharma S.R.L. Via Giacomo Chiesi 43100 Parma Italy	Ciclafast	2%	Cream	Cutaneous use
Italy	Mayne Pharma S.R.L. Via Orazio, 20/22 80122 Napoli Italy	Polipirox	20 mg	Capsule, hard	Oral use
Italy	Mayne Pharma S.R.L. Via Orazio, 20/22 80122 Napoli Italy	Polipirox	20 mg	Suppository	Rectal use
Italy	Mayne Pharma S.R.L. Via Orazio, 20/22 80122 Napoli Italy	Polipirox	20 mg/ml	Solution for injection	Intramuscular use
Italy	Merck Generics Italia S.P.A. Via Aquileia, 35 20092 Cinisello Balsamo (Mi)	Piroxicam	20 mg/1 ml	Solution for injection	Intramuscular use
Italy	Officina Farmaceutica Fiorentina S.R.L. Quartiere Varignano, 12 - 13 - 14 55049 Viareggio (Lu) Italy	Dexicam	10 mg	Capsule	Oral use
Italy	Officina Farmaceutica Fiorentina S.R.L. Quartiere Varignano, 12 - 13 - 14 55049 Viareggio (Lu) Italy	Dexicam	20 mg	Capsule	Oral use
Italy	Officina Farmaceutica Fiorentina S.R.L. Quartiere Varignano, 12 - 13 - 14 55049 Viareggio (Lu) Italy	Dexicam	20 mg	Suppository	Rectal use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	Officina Farmaceutica Fiorentina S.R.L. Quartiere Varignano, 12 - 13 - 14 55049 Viareggio (Lu) Italy	Dexicam	1%	Gel	Cutaneous use
Italy	Pfizer Consumer Health Care S.R.L. Strada Statale 156 Km 50 04010 Borgo San Michele (Lt) Italy	Raia	20 mg	Sublingual Tablet	Oral use
Italy	Pfizer Italia S.R.L. S.S. 156 Km 50 04010 Borgo San Michele (Lt) Italy	Feldene	20 mg	Capsule, hard	Oral use
Italy	Pfizer Italia S.R.L. S.S. 156 Km 50 04010 Borgo San Michele (Lt) Italy	Feldene	20 mg	Suppository	Rectal use
Italy	Pfizer Italia S.R.L. S.S. 156 Km 50 04010 Borgo San Michele (Lt) Italy	Feldene	20 mg	Soluble Tablet	Oral use
Italy	Pfizer Italia S.R.L. S.S. 156 Km 50 04010 Borgo San Michele (Lt) Italy	Feldene	20 mg/1 ml	Solution for injection	Intramuscular use
Italy	Pfizer Italia S.R.L. S.S. 156 Km 50 04010 Borgo San Michele (Lt) Italy	Feldene Cremadol	1%	Cream	Cutaneous use
Italy	Pfizer Italia S.R.L. S.S. 156 Km 50 04010 Borgo San Michele (Lt) Italy	Feldene Fast	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	Pfizer Italia S.R.L. S.S. 156 Km 50 04010 Borgo San Michele (Lt) Italy	Feldene Fast	20 mg	Sublingual Tablet	Oral use
Italy	Pfizer Italia S.R.L. S.S. 156 Km 50 04010 Borgo San Michele (Lt) Italy	Feldene Lipo	1%	Gel	Cutaneous use
Italy	Pliva Pharma S.P.A. Via Tranquillo Cremona 10 20092 Cinisello Balsamo (Mi) Italy	Roxene	1%	Cream	Cutaneous use
Italy	Pliva Pharma S.P.A. Via Tranquillo Cremona 10 20092 Cinisello Balsamo (Mi) Italy	Roxene	20 mg/1 ml	Solution for injection	Intramuscular use
Italy	Pliva Pharma S.P.A. Via Tranquillo Cremona 10 20092 Cinisello Balsamo (Mi) Italy	Roxene	20 mg	Soluble Tablet	Oral use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexin	20 mg	Granules for oral solution	Oral use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexin	20 mg	Suppository	Rectal use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexin	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexin	20 mg	Effervescent Tablet	Oral use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexivel	2 ml	Powder and solvent for solution for injection	Intramuscular use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexivel	20 mg	Capsule, hard	Oral use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexivel	20 mg	Suppository	Rectal use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexivel	1%	Cream	Cutaneous use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Brexivel	20 mg/1 ml	Solution for injection	Intramuscular use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Riacen	10 mg	Capsule, hard	Oral use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Riacen	20 mg	Capsule, hard	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Riacen	20 mg	Suppository	Rectal use
Italy	Promedica S.R.L. Via Palermo, 26/A 43100 Parma Italy	Riacen	1%	Cream	Cutaneous use
Italy	Ratiopharm Gmbh Graf-Arco Strasse 3 D-89070 Ulm Germany	Piroxicam Ratiopharm	20 mg/ml	Solution for injection	Intramuscular use
Italy	Ratiopharm Gmbh Graf-Arco Strasse 3 D-89070 Ulm Germany	Piroxicam Ratiopharm	20 mg	Capsule, hard	Oral use
Italy	Ratiopharm Gmbh Graf-Arco Strasse 3 D-89070 Ulm Germany	Piroxicam Ratiopharm	20 mg	Soluble Tablet	Oral use
Italy	Sandoz S.P.A. Largo Boccioni, 1 21040 Origgio (Va) Italy	Piroxicam Sandoz	20 mg	Suppository	Rectal use
Italy	Sandoz S.P.A. Largo Boccioni, 1 21040 Origgio (Va) Italy	Piroxicam Sandoz	20 mg	Capsule, hard	Oral use
Italy	Sandoz S.P.A. Largo Boccioni, 1 21040 Origgio (Va) Italy	Piroxicam Sandoz	1%	Cream	Cutaneous use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Italy	So.Se.Pharm S.R.L. Societa' Di Servizio Per L'industria Farmaceutica Ed Affini Via Dei Castelli Romani, 22 00040 Pomezia (Rm) Italy	Artroxicam	20 mg	Capsule	Oral use
Italy	So.Se.Pharm S.R.L. Societa' Di Servizio Per L'industria Farmaceutica Ed Affini Via Dei Castelli Romani, 22 00040 Pomezia (Rm) Italy	Artroxicam	20 mg	Suppository	Rectal use
Italy	So.Se.Pharm S.R.L. Societa' Di Servizio Per L'industria Farmaceutica Ed Affini Via Dei Castelli Romani, 22 00040 Pomezia (Rm) Italy	Artroxicam	1%	Cream	Topical use
Italy	So.Se.Pharm S.R.L. Societa' Di Servizio Per L'industria Farmaceutica Ed Affini Via Dei Castelli Romani, 22 00040 Pomezia (Rm) Italy	Artroxicam	1%	Cutaneous foam	Cutaneous use
Italy	Tad Pharma Italia S.R.L. Via Felice Casati, 16 20124 Milano Italy	Errekam	20 mg	Solution for injection	Intramuscular use
Italy	Teva Pharma Italia S.R.L. Viale G. Richard, 7 20143 Milano Italy	Piroxicam	1%	Cream	Cutaneous use
Italy	Winthrop Pharmaceuticals Italia S.R.L. Viale Bodio, 37/B 20158 Milano Italy	Piroxicam Winthrop	20 mg	Capsule, hard	Oral use
Lithuania	Chiesi Farmaceutici S.P.A.	Brexin	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Lithuania	Via Palermo 26/A 43100 Parma Italy Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexin	20 mg/3 mg	Granules for oral solution	Oral use
Lithuania	Boehringer Ingelheim International GmbH Binger Straße 173 55216 Ingelheim Am Rhein Germany	Finalgel Sport	0,5 g/100 g	Gel	Cutaneous use
Lithuania	Egis Pharmaceuticals Ltd. Keresztúri Út 30-38 H-1106 Budapest Hungary	Hotemin	20 mg	Capsule	Oral use
Lithuania	Egis Pharmaceuticals Ltd. Keresztúri Út 30-38 H-1106 Budapest Hungary	Hotemin	20 mg/ml	Solution for injection	Intramuscular use
Lithuania	Egis Pharmaceuticals Ltd. Keresztúri Út 30-38 H-1106 Budapest Hungary	Hotemin	500 mg/50 g	Cream	Cutaneous use
Lithuania	Pharmaceutical Works Jelfa Sa Ul. W.Pola 21 58-500 Jelenia Gora Poland	Piroxicam	20 mg	Coated tablet	Oral use
Lithuania	Pharmaceutical Works Jelfa Sa Ul. W.Pola 21 58-500 Jelenia Gora Poland	Piroxicam	10 mg	Coated tablet	Oral use
Luxembourg	Pfizer S.A.	Feldene	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Luxembourg	17, Boulevards De La Plaine B-1050 Bruxelles Belgium Pfizer S.A.	Feldene	10mg	Capsule	Oral use
Luxembourg	17, Boulevards De La Plaine B-1050 Bruxelles Belgium Pfizer S.A.	Feldene	20 mg	Capsule	Oral use
Luxembourg	17, Boulevards De La Plaine B-1050 Bruxelles Belgium Pfizer S.A.	Feldene	20 mg	Suppository	Rectal use
Luxembourg	17, Boulevards De La Plaine B-1050 Bruxelles Belgium Pfizer S.A.	Feldene	20 mg/ml	Solution for injection	Intramuscular use
Luxembourg	17, Boulevards De La Plaine B-1050 Bruxelles Belgium Pfizer S.A.	Feldene Dispersal	20 mg	Dispersible tablet	Oral use
Luxembourg	Eurogenerics S.A. Esplanade Heysel, B 22 B-1020 Bruxelles Belgium	Lampoflex	10 mg	Capsule	Oral use
Luxembourg	Eurogenerics S.A. Esplanade Heysel, B 22 B-1020 Bruxelles Belgium	Lampoflex	20 mg	Capsule	Oral use
Luxembourg	Eurogenerics S.A.	Lampoflex	0.50%	Gel	Cutaneous use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Luxembourg	Esplanade Heysel B 22 B-1020 Bruxelles Belgium Nycomed Belgium S.A. 615, Chaussee De Gand B-1080 Bruxelles Belgium	Brexine	20 mg	Tablet	Oral use
Luxembourg	Nycomed Belgium S.A. 615, Chaussee De Gand B-1080 Bruxelles Belgium	Brexine	20 mg	Granules	Oral use
Luxembourg	Nycomed Belgium S.A. 615, Chaussee De Gand B-1080 Bruxelles Belgium	Brexine	10 mg	Tablet	Oral use
Luxembourg	Nycomed Belgium S.A. 615, Chaussee De Gand B-1080 Bruxelles Belgium	Brexine	20 mg	Effervescent tablet	Oral use
Luxembourg	Smb Laboratories 26-28 Rue De La Pastorale B-1080 Bruxelles Belgium	Solicam	10 mg	Capsule	Oral use
Luxembourg	Smb Laboratories 26-28 Rue De La Pastorale B-1080 Bruxelles Belgium	Solicam	20 mg	Capsule	Oral use
Luxembourg	Docpharma S.A. Ambachtenlaan 13h B-3001 Heverlee Belgium	Docpiroxi Dispers	20 mg	Dispersible tablet	Oral use
Luxembourg	Rationpharm Gmbh	Piroxicam-Rpm	10 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Luxembourg	Postfach 3380 D-89070 Ulm Germany Rationpharm Gmbh Postfach 3380 D-89070 Ulm Germany	Piroxicam-Rpm	20 mg	Tablet	Oral use
Luxembourg	Hexal AG Industriestrasse 25 D-83607 Holzkirchen Germany	Piroxicam-HEXAL	10 mg	Tablet	Oral use
Luxembourg	Hexal Ag Industriestrasse 25 D-83607 Holzkirchen Germany	Piroxicam-Hexal	20 mg	Tablet	Oral use
Latvia	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexin	20 mg	Granules	Oral use
Latvia	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Brexin	20 mg	Tablet	Oral use
Latvia	Cipla (Uk) Limited 53a High Street Esher Surrey Kt10 9qr United Kingdom	Pirox Gel	0,5 %	Gel	Dermal use
Latvia	Cipla (Uk) Limited 53a High Street Esher Surrey Kt10 9qr United Kingdom	Pirox-20	20 mg	Capsule	Oral use
Latvia	Sopharma Ad	Piroxicam	10 mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Latvia	Iliensko Shose Str. 16 1220 Sofia Bulgaria Sopharma Ad Iliensko Shose Str. 16 1220 Sofia Bulgaria	Piroxicam	20 mg	Capsule	Oral use
Latvia	Pharmaceutical Works Jelfa S.A. Ul. Wincentego Pola 21 58-500 Jelenia Gora Poland	Piroxicam 10 Mg	10 mg	Film-coated tablet	Oral use
Latvia	Pharmaceutical Works Jelfa S.A. Ul. Wincentego Pola 21 58-500 Jelenia Gora Poland	Piroxicam 20 Mg	20 mg	Film-coated tablet	Oral use
Latvia	Tallinna Farmaatsiatehase As 33 Tondi Street Ee – 11316, Tallinn Estonia	Piroxicam Tft	20 mg	Tablet	Oral use
Malta	Bruschettini SRL Via Isonzo 4 16147 Genova Italy	Bruxicam	1g	Cream	Topical use
Malta	Bruschettini SRL Via Isonzo 4 16147 Genova Italy	Bruxicam	20mg	Capsule	Oral use
Malta	Alta Care Laboratories Ltd. 188 Via Ilderbrando Vivanti 00144 Rome Italy	Flodol	1g	Gel	Topical use
Malta	Alta Care Laboratories Ltd.	Flodol	20mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
The Netherlands	188 Via Ilderbrando Vivanti 00144 Rome Italy Actavis B.V. Postbus 313 3740 Ah Baarn Baarnsche Dijk 1 3741 Ln Baarn The Netherlands	Piroxicam Actavis Disper 20 mg	20 mg	Dispersible tablet	Oral use
The Netherlands	Actavis B.V. Postbus 313 3740 Ah Baarn Baarnsche Dijk 1 3741 Ln Baarn The Netherlands	Piroxicam Actavis 10 mg	10 mg	Capsule	Oral use
The Netherlands	Actavis B.V. Postbus 313 3740 Ah Baarn Baarnsche Dijk 1 3741 Ln Baarn The Netherlands	Piroxicam Actavis 20 mg	20 mg	Capsule	Oral use
The Netherlands	Centrafarm Services B.V. Postbus 289 4870 Ag Etten Leur The Netherlands	Piroxicam Cf 10 mg	10 mg	Capsule	Oral use
The Netherlands	Centrafarm Services B.V. Postbus 289 4870 Ag Etten Leur The Netherlands	Piroxicam Cf 20 mg	20 mg	Capsule	Oral use
The Netherlands	Centrafarm Services B.V. Postbus 289 4870 Ag Etten Leur	Piroxicam Disper Cf 20 mg	20 mg	Dispersible tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
The Netherlands	The Netherlands Sandoz B.V Veluwezoom 22 1327 Ah Almere	Piroxicam Sandoz Disper 10 mg	10 mg	Dispersible tablet	Oral use
The Netherlands	The Netherlands Sandoz B.V Veluwezoom 22 1327 Ah Almere	Piroxicam Sandoz Disper 20 mg	20 mg	Dispersible tablet	Oral use
The Netherlands	The Netherlands Sandoz B.V Veluwezoom 22 1327 Ah Almere	Piroxicam Sandoz 20 Mg Zetpil	20 mg	Suppository	Rectal use
The Netherlands	The Netherlands Karib Ltd, Karib House 63-65 Imperial Way Cr9 4qy Croydon, Surrey United Kingdom	Piroxicam Flx 10 mg	10 mg	Capsule	Oral use
The Netherlands	The Netherlands Karib Ltd, Karib House 63-65 Imperial Way Cr9 4qy Croydon, Surrey United Kingdom	Piroxicam Flx 20 mg,	20 mg	Capsule	Oral use
The Netherlands	The Netherlands Katwijk Farma B.V. Postbus 408 2300 Ak Leiden	Piroxicam Katwijk 20 Mg Dispers Tabletten	20 mg	Dispersible tablet	Oral use
The Netherlands	The Netherlands Nycomed Nederland B.V. Nikkelstraat 5 4823 Ae Breda	Brexine Bruis	20 mg	Effervescent tablet	Oral use
The Netherlands	The Netherlands Nycomed Nederland B.V.	Brexine	20 mg	Oral powder	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
The Netherlands	Nikkelstraat 5 4823 Ae Breda The Netherlands Nycomed Nederland B.V. Nikkelstraat 5 4823 Ae Breda The Netherlands	Brexine	20 mg	Tablet	Oral use
The Netherlands	Pharmachemie B.V. Postbus 552 2003 RN Haarlem The Netherlands	Piroxicam Disp. 10 PCH	10 mg	Dispersible tablet	Oral use
The Netherlands	Pharmachemie B.V. Postbus 552 2003 RN Haarlem The Netherlands	Piroxicam Disp. 20 PCH	20 mg	Dispersible tablet	Oral use
The Netherlands	Pharmachemie B.V. Postbus 552 2003 RN Haarlem The Netherlands	Piroxicam 10 PCH	10 mg	Capsule	Oral use
The Netherlands	Pharmachemie B.V. Postbus 552 2003 RN Haarlem The Netherlands	Piroxicam 20 PCH	20 mg	Capsule	Oral use
The Netherlands	Ratiopharm Nederland Bv, Postbus 2062 1500 Gb Zaandam The Netherlands	Piroxicam Ratiopharm Dispergeerbaar 20 Mg	20 mg	Dispersible tablet	Oral use
The Netherlands	Ratiopharm Nederland Bv, Postbus 2062 1500 Gb Zaandam The Netherlands	Piroxicam Ratiopharm 10 Mg	10 mg	Capsule	Oral use
The Netherlands	Ratiopharm Nederland Bv,	Piroxicam	10 mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	Postbus 2062 1500 Gb Zaandam The Netherlands	Ratiopharm 10 Mg			
The Netherlands	Ratiopharm Nederland Bv, Postbus 2062 1500 Gb Zaandam The Netherlands	Piroxicam Ratiopharm 20 Mg	20 mg	Capsule	Oral use
The Netherlands	Ratiopharm Nederland Bv, Postbus 2062 1500 Gb Zaandam The Netherlands	Piroxicam Ratiopharm 20 Mg	20 mg	Capsule	Oral use
The Netherlands	Sanofi-Synthelabo B.V. Postbus 2043 2800 Bd Gouda The Netherlands	Piroxicam Albic 10 Mg	10 mg	Capsule	Oral use
The Netherlands	Sanofi-Synthelabo B.V. Postbus 2043 2800 Bd Gouda The Netherlands	Piroxicam Albic 20 Mg	20 mg	Capsule	Oral use
The Netherlands	Wise Pharmaceuticals Ltd. Hamwells Business Park Unit No.7, Hardicker Street M19 2rb Manchester United Kingdom	Piroxicam 10 Mg	10 mg	Capsule	Oral use
The Netherlands	Wise Pharmaceuticals Ltd. Hamwells Business Park Unit No.7, Hardicker Street M19 2rb Manchester United Kingdom	Piroxicam 20 Mg	20 mg	Capsule	Oral use
Norway	Pfizer PO Box 3 N-1324 Lysaker	Felden	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Norway	Norway Nycomed Pharma As P.O. Box 205, N-1372 Asker 0010 Oslo	Brexidol	20 mg	Tablet	Oral use
Norway	Norway Nycomed Pharma As P.O. Box 205, N-1372 Asker 0010 Oslo	Brexidol	20 mg	Oral powder in sachet	Oral use
Norway	Norway Alpharma P.O. Box 158 Skøyen N-0212 Oslo	Pirox	20 mg	Tablet	Oral use
Norway	Norway Merck NM P.O.Box 23033 S-10435 Stockholm Sweden	Piroxicam Merck Nm	20 mg	Tablet	Oral use
Poland	Apotex Europe Ltd. Rowan House 41 London Street Reading, Berkshire, Rg1 4ps	Apo-Piroxicam 10	10 mg	Capsule	Oral use
Poland	Apotex Europe Ltd. Rowan House 41 London Street Reading, Berkshire, Rg1 4ps	Apo-Piroxicam 20	20 mg	Capsule	Oral use
Poland	Pfizer Europe MA EEIG Sandwich Kent Ct13 9nj United Kingdom	Feldene	20 mg/ml	Solution for injection	Parenteral use
Poland	Glaxosmithkline Pharmaceuticals S.A Grunwaldzka St. 189	Piroxicam 10	10 mg	Suppository	Rectal use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Poland	60-322, Poznań Poland Glaxosmithkline Pharmaceuticals S.A Grunwaldzka St. 189 60-322, Poznań Poland	Piroxicam 20	20 mg	Suppository	Rectal use
Poland	60-322, Poznań Poland Glaxosmithkline Pharmaceuticals S.A Grunwaldzka St. 189 60-322, Poznań Poland	Piroxicam	50 mg/g	Ointment	Cutaneous use
Poland	60-322, Poznań Poland Glaxosmithkline Pharmaceuticals S.A Grunwaldzka St. 189 60-322, Poznań Poland	Piroxicam	50 mg/g	Gel	Cutaneous use
Poland	Przedsiębiorstwo Farmaceutyczne Jelfa S.A. Wincentego St. Pola 21 58-500, Jelenia Góra Poland	Piroxicam Jelfa	10 mg	Film-coated tablet	Oral use
Poland	Przedsiębiorstwo Farmaceutyczne Jelfa S.A. Wincentego St. Pola 21 58-500, Jelenia Góra Poland	Piroxicam Jelfa	20 mg	Film-coated tablet	Oral use
Poland	Egis Pharmaceuticals Ltd. Kereszturi Ut 30-38 H-1106, Budapest Hungary	Hotemin	10 mg	Capsule	Oral use
Poland	Egis Pharmaceuticals Ltd. Kereszturi Ut 30-38 H-1106, Budapest Hungary	Hotemin	20 mg	Capsule, hard	Oral use
Poland	Egis Pharmaceuticals Ltd. Kereszturi Ut 30-38	Hotemin	20 mg/ml	Solution for injection	Parenteral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Poland	H-1106, Budapest Hungary Torrex Chiesi Polska Sp. z o.o. ul. Biala 3 00-895 Warszawa Poland	Flamexin	20 mg	Powder for solution for injection	Parenteral use
Poland	Torrex Chiesi Polska Sp. z o.o. ul. Biala 3 00-895 Warszawa Poland	Flamexin	20 mg	Tablet	Oral use
Poland	Boehringer Ingelheim International Gmbh Binger Str 173 55216, Ingelheim Am Rhein Germany	Finalgel Sport	5 mg/g	Gel	Cutaneous use
Poland	Sankyo Pharma Gmbh MünchenZielstattstr. 48 81379, München	Mobilat P Cream	5 mg/g	Cream	Cutaneous use
Portugal	Neo-Farmacêutica, Lda. Av. D. João Ii Lote 1.02.2.1 D - 2° 1990-090 Lisboa Portugal	Brexin	20 mg	Tablet	Oral use
Portugal	Neo-Farmacêutica, Lda. Av. D. João Ii Lote 1.02.2.1 D - 2° 1990-090 Lisboa Portugal	Brexin	20 mg	Effervescent tablet	Oral use
Portugal	Neo-Farmacêutica, Lda. Av. D. João Ii Lote 1.02.2.1 D - 2° 1990-090 Lisboa Portugal	Brexin	20 mg	Granules	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Portugal	Laboratórios Pfizer, Lda. Empreendimento Lagoas Park Edifício 10 2740-271 Porto Salvo Portugal	Feldene	20 mg	Capsule	Oral use
Portugal	Laboratórios Pfizer, Lda. Empreendimento Lagoas Park Edifício 10 2740-271 Porto Salvo Portugal	Feldene	20 mg	Dispersible tablet	Oral use
Portugal	Laboratórios Pfizer, Lda. Empreendimento Lagoas Park Edifício 10 2740-271 Porto Salvo Portugal	Feldene	5 mg/g	Gel	Cutaneous use
Portugal	Laboratórios Pfizer, Lda. Empreendimento Lagoas Park Edifício 10 2740-271 Porto Salvo Portugal	Feldene	20 mg/1 ml	Solution for injection	Intramuscular use
Portugal	Laboratórios Pfizer, Lda. Empreendimento Lagoas Park Edifício 10 2740-271 Porto Salvo Portugal	Feldene	20 mg	Suppository	Rectal use
Portugal	A. Menarini Portugal - Farmacêutica, S.A. Quinta Da Fonte Edifício D. Manuel I - Piso 2 Rua Dos Malhões Nº 1 2770-071 Paço De Arcos Portugal	Flexar	20 mg	Capsule	Oral use
Portugal	A. Menarini Portugal - Farmacêutica, S.A. Quinta Da Fonte Edifício D. Manuel I - Piso 2	Flexar	20 mg	Dispersible tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Portugal	Rua Dos Malhões Nº 1 2770-071 Paço De Arcos Portugal A. Menarini Portugal - Farmacêutica, S.A. Quinta Da Fonte Edifício D. Manuel I - Piso 2	Flexar	5 mg/g	Gel	Cutaneous use
Portugal	Rua Dos Malhões Nº 1 2770-071 Paço De Arcos Portugal A. Menarini Portugal - Farmacêutica, S.A. Quinta Da Fonte Edifício D. Manuel I - Piso 2	Flexar	20 mg	Suppository	Rectal use
Portugal	Rua Dos Malhões Nº 1 2770-071 Paço De Arcos Portugal A. Menarini Portugal - Farmacêutica, S.A. Rua General Ferreira Martins, 8 - 7º Miraflores 1495-137 Algés Portugal	Flexar	20 mg/1 ml	Solution for injection	Via intramuscular
Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada Nacional 117-2 Edifícios Azevedos - Alfragide 2724-503 Amadora Portugal	Flogocan 10	10 mg	Capsule	Oral use
Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A. Estrada Nacional 117-2 Edifícios Azevedos - Alfragide 2724-503 Amadora Portugal	Flogocan 20	20 mg	Capsule	Oral use
Portugal	Ratiopharm - Comércio E Indústria De Produtos Farmacêuticos, Lda. Rua Quinta Do Pinheiro - Edifício Tejo - 6º Piso 2790-143 Carnaxide Portugal	Piroxicam Ratiopharm 10 Mg Comprimidos	10 mg	Tablet	Oral use
Portugal	Ratiopharm - Comércio E Indústria De Produtos	Piroxicam	20 mg	Tablet	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	Farmacêuticos, Lda. Rua Quinta Do Pinheiro - Edificio Tejo - 6º Piso 2790-143 Carnaxide Portugal	Ratiopharm 20 Mg Comprimidos			
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro De Pavia, 1 - 1º Venda Nova 2700-547 Amadora Portugal	Reumoxican	10 mg	Capsule	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro De Pavia, 1 - 1º Venda Nova 2700-547 Amadora Portugal	Reumoxican	20 mg	Capsule	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro De Pavia, 1 - 1º Venda Nova 2700-547 Amadora Portugal	Reumoxican	10 mg	Dispersible tablet	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro De Pavia, 1 - 1º Venda Nova 2700-547 Amadora Portugal	Reumoxican	20 mg	Dispersible tablet	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro De Pavia, 1 - 1º Venda Nova 2700-547 Amadora Portugal	Reumoxican	10 mg/g	Cream	Cutaneous use
Portugal	Biosaúde - Produtos Farmacêuticos, Lda Av. José Malhoa - Edifício Malhoa Plaza Nº 2, Piso-Escritório 2.2 1070-325 Lisboa Portugal	Remisil	5 mg/g	Gel	Cutaneous use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro De Pavia, 1 - 1º - Venda Nova 2700-547 Amadora	Reumoxican	20 mg/1 ml	Solution for injection	Intramuscular use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Portugal	Portugal Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro De Pavia, 1 - 1º - Venda Nova 2700-547 Amadora	Reumoxican	20 mg	Suppository	Rectal use
Portugal	Portugal Laboratórios Basi - Indústria Farmacêutica, S.A. Rua Do Padrão, 98 3000-312 Coimbra	Roxazin	20 mg	Capsule	Oral use
Portugal	Portugal Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro De Pavia, 1 - 1º - Venda Nova 2700-547 Amadora	Reumoxican S.A.	20 mg	Capsule	Oral use
Portugal	Portugal Cinfa Portugal, Lda. Av. Tomás Ribeiro, 43 - Bloco 2, 3º F - Edifício Neopark 2790-221 Carnaxide	Piroxicam Cinfa 20 Mg Comprimidos Dispersiveis	20 mg	Dispersible tablet	Oral use
Romania	Portugal Bruschettini S.R.L. Via Isonzo 6 16147 Genova	Bruxicam 0,5%	0.50%	Eye Drops, Solution	Ocular
Romania	Italy Egis Pharmaceuticals Plc Kereszturi Ut 30-38 H-1106 Budapest	Hotemin	20mg/MI - 1ml	Solution For Injection	Intramuscular
Romania	Hungary Pfizer Europe MA EEIG Ramsgate Road Sandwich Kent CT 13 9 NJ	FELDENE 20mg/MI	20mg/MI - 1ml	Solution For Injection	Intramuscular
Romania	United Kingdom Boehringer Ingelheim Pharma Gmbh & Co.Kg, Binger Strasse 173	Finalgel	5mg/G	Gel	Cutaneous

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Romania	D-55216 Ingelheim Am Rhein Germany Chiesi Farmaceutici Spa, Via Palermo, 26/A 43100 Parma Italy	Flamexin	20mg	Tablet	Oral
Romania	Chiesi Farmaceutici Spa, Via Palermo, 26/A 43100 Parma Italy	Flamexin	20mg	Effervescent Tablet	Oral
Romania	Chiesi Farmaceutici Spa, Via Palermo, 26/A 43100 Parma Italy	Flamexin	20mg	Powder For Oral Solution	Oral
Romania	S.C. Slavia Pharm S.R.L. Str. Stirbei Voda Nr. 53-55 Sector 1, Bucuresti Romania	Piroxsal Gel 0,5g%	0,5g%	Gel	Cutaneous
Romania	S.C. Meduman S.A. Aleea Eroilor Nr.28 Viseu De Sus Jud. Maramures Romania	N-Piroxicam 20mg	20mg	Tablet	Oral
Romania	S.C. Antibiotice S.A. Str. Valea Lupului Nr.1 Iasi Romania	Piroxicam	3%	Cream	Local
Romania	S.C. Laropharm S.R.L. Sos. Alexandriei 145a Comuna Bragadiru Jud. Ilfov Romania	Piroxicam	20mg	Tablet	Oral

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Romania	S.C. Antibiotice S.A. Str. Valea Lupului Nr.1 Iasi Romania	Piroxicam	0.50%	Gel	Cutaneous
Romania	S.C. Antibiotice S.A. Str. Valea Lupului Nr.1 Iasi Romania	Piroxicam 20mg	20mg	Suppository	Rectal
Romania	S.C. Sintofarm S.A. Str. Ziduri Intre Vii Nr.22 Sector 2, Bucurest Romania	Piroxicam 20mg	20mg	Suppository	Rectal
Romania	S.C. Sintofarm S.A. Str. Ziduri Intre Vii Nr.22 Sector 2, Bucurest Romania	Piroxicam 20mg	20mg	Tablet	Oral
Romania	S.C. Terapia S.A. Str. Fabricii Nr.124 Cluj-Napoca Jud. Cluj Romania	Piroxicam	20mg	Tablet	Oral
Romania	S.C. Fabiol S.A. B-UI Timisoara Nr.50 Sector 6, Bucuresti Romania	Piroxicam	20mg	Tablet	Oral
Romania	S.C. Ac Helcor S.R.L. Str. Victor Babes Nr.50 Baia Mare, Jud Maramures Romania	Piroxicam 20mg	20mg	Tablet	Oral
Romania	S.C. Arena Group S.A. Str. Stefan Mihaileanu Nr.31 Etaj 1, Ap. 1	Piroxicam 20mg	20mg	Tablet	Oral

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Romania	Sector 2, Bucuresti Romania S.C. Antibiotice S.A. Str. Valea Lupului Nr.1 Iasi Romania	Piroxicam 40mg	40mg	Suppository	Rectal
Romania	S.C. Labormed-Pharma S.A. Splaiul Independentei Nr. 319e Sector 6, Bucuresti Romania	Piroxicam LPH 20mg	20mg	Tablet	Oral
Romania	S.C. Mark Pharmaceuticals S.R.L. Str Moara De Foc Nr. 35 Iasi, Jud Iasi Romania	Piroxicam Mk Crema	3%	Cream	Cutaneous
Romania	S.C. Mark Pharmaceuticals S.R.L. Str Moara De Foc Nr. 35 Iasi, Jud Iasi Romania	Piroxicam Mk Gel	1%	Gel	Cutaneous
Romania	S.C. Slavia Pharm S.R.L. Str. Stirbei Voda Nr. 53-55 Sector 1, Bucuresti Romania	Piroxsal	20mg	Tablet	Oral
Romania	S.C. Slavia Pharm S.R.L. Str. Stirbei Voda Nr. 53-55 Sector 1, Bucuresti Romania	Piroxsal Gel 0,5g%	0,5g%	Gel	Cutaneous
Romania	Ozone Laboratories Ltd. 38 Princes Court 88 Brompton Road Knightsbridge, SW3 1ES London United Kingdom	Piroxicam 1%	1%	Gel	Cutaneous
Romania	Ozone Laboratories Ltd.	Piroxicam 20mg	20mg	Tablet	Oral

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Romania	38 Princes Court 88 Brompton Road Knightsbridge, SW3 1ES London United Kingdom Ozone Laboratories Ltd. 38 Princes Court 88 Brompton Road Knightsbridge, SW3 1ES London United Kingdom				
Sweden	Nycomed Ab Box 27264 Se-102 53 Stockholm Sweden	Piroxicam 3% Brexidol	3% 20 mg	Cream Tablet	Cutaneous Oral use
Sweden	Nycomed Ab Box 27264 Se-102 53 Stockholm Sweden	Brexidol	20 mg	Powder for oral solution	Oral use
Sweden	Merck Nm Ab Box 23033 Se-104 35 Stockholm Sweden	Piroxicam Merck Nm	10 mg	Tablet	Oral use
Sweden	Merck Nm Ab Box 23033 Se-104 35 Stockholm Sweden	Piroxicam Merck Nm	20 mg	Tablet	Oral use
Slovakia	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma Italy	Flamexin 20 Mg	20 mg	Granulát	oral use
Slovakia	Chiesi Farmaceutici S.P.A. Via Palermo 26/A 43100 Parma	Flamexin 20 Mg	20 mg	Tableta	oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Slovakia	Italy Egis Gyógyszergyár Nyrt. Keresztúri U. 30-38 1106 Budapest Hungary	Hotemin	1x50 g/0,5 g	Dermálny krém	topical use
Slovakia	Egis Gyógyszergyár Nyrt. Keresztúri U. 30-38 1106 Budapest Hungary	Hotemin	10 mg	Kapsula	oral use
Slovakia	Egis Gyógyszergyár Nyrt. Keresztúri U. 30-38 1106 Budapest Hungary	Hotemin 20mg	20 mg	Injekčný roztok	parenteral use
Slovakia	Pro.Med.Cs Praha A.S. Telčská 114000 Praha 4 Czech Republic	Pro-Roxikam 10 Mg	10 mg	Tableta	oral use
Slovakia	Pro.Med.Cs Praha A.S. Telčská 114000 Praha 4 Czech Republic	Pro-Roxikam 20 Mg	20 mg	Tableta	oral use
Slovenia	Krka, Tovarna Zdravil, D.D., Šmarješka Cesta 6 Si-8501 Novo Mesto Slovenia	Erazon	20 mg	Capsule, hard	Oral use
Slovenia	Krka, Tovarna Zdravil, D.D., Šmarješka Cesta 6 Si-8501 Novo Mesto Slovenia	Erazon	10 mg/1 g	Cream	Cutaneous use
Slovenia	Krka, Tovarna Zdravil, D.D., Šmarješka Cesta 6 Si-8501 Novo Mesto	Erazon	10 mg/1 g	Gel	Cutaneous use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
Slovenia	Slovenia Krka, Tovarna Zdravil, D.D., Šmarješka Cesta 6 Si-8501 Novo Mesto Slovenia	Erazon	20 mg	Suppository	Rectal use
United Kingdom	Pfizer Limited Walton Oaks, Dorking Road Walton-On-The-Hill Surrey KT20 7NS United Kingdom	Feldene Capsules 10 Mg	10mg	Capsule	Oral use
United Kingdom	Pfizer Limited Walton Oaks, Dorking Road Walton-On-The-Hill Surrey KT20 7NS United Kingdom	Feldene 20 (20mg Capsules)	20mg	Capsule	Oral use
United Kingdom	Pfizer Limited Walton Oaks, Dorking Road Walton-On-The-Hill Surrey KT20 7NS United Kingdom	Feldene Dispersable Tablets 10mg	10mg	Tablet for oral solution	Oral use
United Kingdom	Pfizer Limited Walton Oaks, Dorking Road Walton-On-The-Hill Surrey KT20 7NS United Kingdom	Feldene Dispersible Tablets-20 Mg	20mg	Tablet for oral solution	Oral use
United Kingdom	Pfizer Limited Walton Oaks, Dorking Road Walton-On-The-Hill Surrey KT20 7NS United Kingdom	Feldene Gel 0.5% W/W	0.5% w/w	Gel	Cutaneous use
United Kingdom	Pfizer Limited Walton Oaks, Dorking Road	Feldene Intramuscular	20mg/ml	Solution for injection	Intramuscular use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	Walton-0n-The-Hill Surrey KT20 7NS United Kingdom	Injection 20mg/MI			
United Kingdom	Pfizer Limited Walton Oaks, Dorking Road Walton-0n-The-Hill Surrey KT20 7NS United Kingdom	Feldene Melt 20mg Tablets	20mg	Tablet for oral solution	Oral use
United Kingdom	Actavis Uk Limited Whiddon Vally Barnstaple Devon Ex32 8ns United Kingdom	Piroxicam Capsules 10mg	10mg	Capsule	Oral use
United Kingdom	Actavis Uk Limited Whiddon Vally Barnstaple Devon Ex32 8ns United Kingdom	Piroxicam Capsules 20mg	20mg	Capsule	Oral use
United Kingdom	Clonmel Healthcare Limited Waterford Road Clonmel, Co. Tipperary, Ireland	Kentene,Piroflam, Piroflex	10mg	Capsule, hard	Oral use
United Kingdom	Clonmel Healthcare Limited Waterford Road Clonmel, Co. Tipperary, Ireland	Kentene,Piroflam, Piroflex	20mg	Capsule, hard	Oral use
United Kingdom	Sandoz Limited Unit 37, Woolmer Way Bordon Hampshire Gu35 9qe United Kingdom	Piroxicam 10 Mg Capsules	10mg	Capsule	Oral use
United Kingdom	Sandoz Limited	Piroxicam 20 Mg	20mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
	Unit 37, Woolmer Way Bordon Hampshire Gu35 9qe United Kingdom	Capsules			
United Kingdom	Pharmvit Limited Unit 13, Metropolitan Centre Derby Road, Greenford Middlesex UB6 8UJ United Kingdom	Piroxicam 10mg Capsules Bp	10mg	Capsule, hard	Oral use
United Kingdom	Pharmvit Limited Unit 13, Metropolitan Centre Derby Road, Greenford Middlesex UB6 8UJ United Kingdom	Piroxicam 20mg Capsules Bp	20mg	Capsule, hard	Oral use
United Kingdom	Generics Uk Limited Albany Gate, Darkes Lane, Potters Bar Herts EN6 1AG United Kingdom	Piroxicam Capsules 10mg	10mg	Capsule	Oral use
United Kingdom	Generics Uk Limited Albany Gate, Darkes Lane, Potters Bar Herts EN6 1AG United Kingdom	Piroxicam Capsules 20mg	20mg	Capsule	Oral use
United Kingdom	Generics Uk Limited Albany Gate, Darkes Lane, Potters Bar Herts EN6 1AG United Kingdom	Piroxicam Dispersible Tablets 10mg	10mg	Tablet for oral solution	Oral use
United Kingdom	Generics Uk Limited Albany Gate, Darkes Lane, Potters Bar Herts EN6 1AG United Kingdom	Piroxicam Dispersible Tablets 20mg	20mg	Tablet for oral solution	Oral use
United Kingdom	Waymade Plc Sovereign House	Piroxicam 0.5% Gel	0.5% w/w	Gel	Cutaneous use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
United Kingdom	Miles Gray Road Basildon, Essex SS14 3FR United Kingdom Neolab Limited 57 High Street Odiham, Hampshire RG29 1LF United Kingdom	Piroxicam 0.5% Gel	0.5% w/w	Gel	Cutaneous use
United Kingdom	Neolab Limited 57 High Street Odiham, Hampshire RG29 1LF United Kingdom	Piroxicam 0.5% Gel	0.5% w/w	Gel	Cutaneous use
United Kingdom	Dr Reddy's Laboratories (Uk) Limited 6 Riverview Road Beverley, E Yorks HU17 0LD United Kingdom	Piroxicam 0.5% Gel	0.5% w/w	Gel	Cutaneous use
United Kingdom	Trinity-Chiesi Pharmaceuticals Limited Cheadlw Royal Business Park Highfield, Cheadle SK8 3GY United Kingdom	Brexidol 20mg Tablets	20mg	Tablet	Oral use
United Kingdom	Trinity-Chiesi Pharmaceuticals Limited Cheadlw Royal Business Park Highfield, Cheadle SK8 3GY United Kingdom	Brexidol 20 Mg Effervescent Tablets	20mg	Effervescent tablet	Oral use
United Kingdom	Pliva Pharma Limited Vision House, Bedford Road Petersfield, Hampsire GU32 3QB United Kingdom	Piroxicam 0.5% Gel	0.5% w/w	Gel	Cutaneous use
United Kingdom	Tillomed Laboratories Limited 3 Howard Road, Eaton Socon St. Neots, Cambs PE19 3ET United Kingdom	Pirozip 10	10mg	Capsule	Oral use
United Kingdom	Tillomed Laboratories Limited	Pirozip 20	20mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
United Kingdom	3 Howard Road, Eaton Socon St. Neots, Cambs PE19 3ET United Kingdom Manx Healthcare Taylor Group House Wedgnock Lane Warwick CV34 5YA United Kingdom	Piroxicam Gel 0.5%W/W	0.5% w/w	Gel	Cutaneous use
United Kingdom	Teva Pharma Bv Industrieweg 23 Po Box 217 3640 Ae Mijdrecht The Netherlands	Flamatrol 10mg Capsules	10mg	Capsule	Oral use
United Kingdom	Teva Pharma Bv Industrieweg 23 Po Box 217 3640 Ae Mijdrecht The Netherlands	Flamatrol 20mg Capsules	20mg	Capsule	Oral use
United Kingdom	Pfizer Consumer Healthcare Walton Oaks Dorking Road Walton-0n-The-Hill Surrey KT20 7NS United Kingdom	Feldene P Gel	0.5% w/w	Gel	Cutaneous use
United Kingdom	Crescent Pharma Limited Units 3&4, Quidhampton Business Units Polhampton Lane Overton, Hampshire RG25 3ED United Kingdom	Piroxicam Capsules Bp 10mg	10mg	Capsule	Oral use
United Kingdom	Crescent Pharma Limited Units 3&4, Quidhampton Business Units Polhampton Lane	Piroxicam Capsules Bp 20mg	20mg	Capsule	Oral use

<u>Member State</u>	<u>Marketing Authorisation Holder</u>	<u>Invented name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>
United Kingdom	Overton, Hampshire RG25 3ED United Kingdom Strides Arcolab International Limited 201 Jersey Road Isleworth, Middx TW7 4QJ United Kingdom	Piroxicam 10mg Capsules	10mg	Capsule	Oral use
United Kingdom	Strides Arcolab International Limited 201 Jersey Road Isleworth, Middx TW7 4QJ United Kingdom	Piroxicam 20mg Capsules	20mg	Capsule	Oral use

ANNEX II

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

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF PIROXICAM CONTAINING MEDICINAL PRODUCTS (see Annex I)

Piroxicam is a non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic and antipyretic properties. Piroxicam is authorised in the European Union following national marketing procedures.

Further to a request from the European Commission the CHMP reviewed safety data on non-selective NSAIDs. This review, which concluded in October 2005, did not reveal any new safety concerns for the class of NSAIDs as a whole. However the Committee adopted recommendations for changes to the product information, or so called “key elements” during this review which reflect a common position on well known safety issues in the product information of the non-selective NSAIDs. These key elements were published on the EMEA website (Doc ref: EMEA/CHMP/343456/2005).

However a need to further evaluate the benefit/risk balance of some non-selective NSAIDs including piroxicam was identified. This review was finalised in June 2006. The review found that limited epidemiological data and spontaneous adverse drug reaction data provided a signal of increased risk of gastrointestinal and skin reactions (including life-threatening bullous reactions) relative to other non-selective NSAIDs. The CHMP considered that the assessment raised concerns on the benefit/risk balance of piroxicam and informed the European Commission accordingly. The CHMP also made recommendations for changes, or so called “key elements”, to be included in the product information of piroxicam, as well as for some other non-selective NSAIDs which were published on the EMEA website in September 2006 (Doc ref: EMEA/CHMP/381615/2006).

The European Commission considered it to be in the interest of public health to perform a new benefit/risk assessment of piroxicam. Therefore, the European Commission sent a notification that was received by the EMEA on 2 August 2006 and a referral under Article 31 of Directive 2001/83/EC, as amended was started on 21 September 2006. The European Commission requested the CHMP to give its opinion on whether the marketing authorisations for medicinal products containing piroxicam should be maintained, varied, suspended or revoked.

The CHMP reviewed the data submitted by Marketing Authorisation Holders from clinical trials, epidemiological studies, and spontaneous reporting of adverse drug reactions.

The CHMP concluded on 21 June 2007 that epidemiological studies suggest that systemic formulations of piroxicam are associated with a higher risk of serious gastrointestinal toxicity, relative to other NSAIDs, and a higher risk of serious skin reactions (SCAR) than other non-oxicam NSAIDs. Therefore the Committee has made a number of recommendations as outlined below. These recommendations build on the previous key elements published for piroxicam in September 2006 and must be implemented in the product information.

With regards to topical formulations of piroxicam, the CHMP agreed that no restrictions were necessary. The use of topical NSAIDs is accompanied by a markedly reduced systemic exposure compared to systemic dosing and therefore a lower rate of systemic adverse events is expected with use of topical formulations. As such the below outlined recommendations only apply to systemic formulations of piroxicam:

- piroxicam should not be used for treatment of any acute condition due to the long half life of 50 hours and the safety profile, since equally effective and safer therapies are available;
- the benefits of piroxicam outweigh the risks in the symptomatic relief of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis;
- piroxicam is no longer a first line option should an NSAID be indicated;
- prescription of piroxicam should only be initiated by those physicians with experience in diagnostic evaluation and treatment of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis;

- new contraindications and strengthened warnings have been added to the Summary of Product characteristics and Package Leaflet in order to limit exposure of piroxicam to those patients without risk factors for gastrointestinal and skin reactions;
- further risk minimisation measures include limitation of the dose of piroxicam to 20 mg per day, and recommendations to treat patients for the shortest time possible to relieve symptoms with review within 14 days. Combination therapy with gastro-protective agents (e.g. misoprostol or proton pump inhibitors) should also be carefully considered for all patients and in particular for the elderly.

The CHMP agreed that the recommendations of article 5(3) of regulation (EC) no 726/2004 issued in October 2006 and published on the EMEA website (Doc. Ref. EMEA/413136/2006) remain valid for piroxicam containing medicinal products. The review concluded that a small increase in the absolute risk for thrombotic events associated with non-selective NSAIDs cannot be excluded although the overall risk benefit/balance remains positive.

GROUNDINGS FOR AMENDMENT OF THE SUMMARY OF PRODUCT CHARACTERISTICS

Whereas

- The CHMP considered the referral made under article 31 of Directive 2001/83/EC, as amended, for medicinal products containing piroxicam.
- In view of the available data, the Committee concluded that there is an increased risk of gastrointestinal and serious skin reactions associated with systemic formulations of piroxicam when compared to other NSAIDs as a group.
- The CHMP considered that the benefit/risk balance for systemic formulations of piroxicam is positive in the treatment of symptomatic relief of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis; however the CHMP considered that the benefit/risk balance of piroxicam in the treatment of acute conditions is negative and that these indications should be revoked. A number of restrictions on use, strengthened warnings and contraindications have been added to the Summary Product Characteristics and Package Leaflet in relation to gastrointestinal and skin safety.
- The CHMP concluded that the benefit/risk balance of systemic formulations of piroxicam containing medicinal products in the agreed restricted indications is favourable.
- The CHMP agreed that no restrictions were required with regards to topical formulations of piroxicam and the benefit/risk balance remains favourable.

As a consequence, the CHMP has recommended to maintain the Marketing Authorisations for all medicinal products referred to in Annex I of the Opinion and to amend the relevant sections of the Summary of Product Characteristics and Package Leaflet of systemic formulations of piroxicam, as set out in Annex III of the Opinion in accordance with Article 31(2) of Directive 2001/83/EC, as amended.

ANNEX III

AMENDMENTS TO THE SUMMARY OF PRODUCT CHARACTERISTICS AND PACKAGE LEAFLET

Note: These sections of the Summary of Product Characteristics are the ones that were annexed to the Commission Decision on this Article 31 referral. The text was valid at that time.

These sections of the Package Leaflet are the ones that were 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.

**AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE SUMMARY
OF PRODUCT CHARACTERISTICS
FOR SYSTEMIC FORMULATIONS OF PIROXICAM CONTAINING MEDICINAL
PRODUCTS**

4.1 Therapeutic Indications

Indications regarding osteoarthritis, rheumatoid arthritis and ankylosing spondylitis should read as follows:

“Piroxicam is indicated for symptomatic relief of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis.

Due to its safety profile (see sections 4.2, 4.3 and 4.4), piroxicam is not a first line option should an NSAID be indicated. The decision to prescribe piroxicam should be based on an assessment of the individual patient's overall risks (see sections 4.3 and 4.4).”

The following indications must be deleted from this section:

Acute Gout

Primary dysmenorrhea

Post-operative pain

Dental treatment and in the course of infections

Relief of fever and pain associated with acute upper respiratory tract inflammation.

Acute musculoskeletal disorders (e.g bursitis, tendonitis)

Acute post-traumatic disorders.

Radiculgia

4.2 Posology and Method of administration

Posology relating to the indications as outlined in section 4.1 should read as follows:

“The prescription of piroxicam should be initiated by physicians with experience in the diagnostic evaluation and treatment of patients with inflammatory or degenerative rheumatic diseases.

The maximum recommended daily dose is 20 mg.

Undesirable effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms. The benefit and tolerability of treatment should be reviewed within 14 days. If continued treatment is considered necessary, this should be accompanied by frequent review.

Given that piroxicam has been shown to be associated with an increased risk of gastrointestinal complications, the possible need for combination therapy with gastro-protective agents (e.g. misoprostol or proton pump inhibitors) should be carefully considered, in particular for elderly patients.”

Posology relating to the following indications are to be deleted from this section in line with Section 4.1:

Acute Gout

Primary dysmenorrhoea,

Post-operative pain

Following dental treatment and in the course of infections

Relief of fever and pain associated with acute upper respiratory tract inflammation.

Acute musculoskeletal disorders(e.g bursitis, tendonitis)

Acute post-traumatic disorders.

Radiculgia

4.3 Contraindications

...[]...

- *“History of gastro-intestinal ulceration, bleeding or perforation.*
- *Patient history of gastrointestinal disorders that predispose to bleeding disorders such as ulcerative colitis, Crohn’s disease, gastrointestinal cancers or diverticulitis.*
- *Patients with active peptic ulcer, inflammatory gastrointestinal disorder or gastrointestinal bleeding.*
- *Concomitant use with other NSAIDs, including COX-2 selective NSAIDs and acetyl-salicylic acid at analgesic doses.*
- *Concomitant use with anticoagulants.*
- *History of previous serious allergic drug reaction of any type, especially cutaneous reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.*
- *Hypersensitivity to the active substance, previous skin reaction (regardless of severity) to piroxicam, other NSAIDs and other medications.”*

...[]...

4.4 Special Warnings and Special Precautions for Use

...[]...

“Undesirable effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms.

The clinical benefit and tolerability should be re-evaluated periodically and treatment should be immediately discontinued at the first appearance of cutaneous reactions or relevant gastrointestinal events.”

...[]...

...[]...

“Gastrointestinal (GI) Effects, Risk of GI Ulceration, Bleeding, and Perforation.

NSAIDs, including piroxicam, can cause serious gastrointestinal events including bleeding, ulceration, and perforation of the stomach, small intestine or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs.

NSAID exposures of both short and long duration have an increased risk of serious GI event. Evidence from observational studies suggests that piroxicam may be associated with a high risk of serious gastrointestinal toxicity, relative to other NSAIDs.

Patients with significant risk factors for serious GI events should be treated with piroxicam only after careful consideration (See sections 4.3 and below).

The possible need for combination therapy with gastro-protective agents (e.g. misoprostol or proton pump inhibitors) should be carefully considered. (see section 4.2).

Serious GI Complications

Identification of at-risk subjects

The risk for developing serious GI complications increases with age. Age over 70 years is associated with high risk of complications. The administration to patients older than 80 years should be avoided.

Patients taking concomitant oral corticosteroids, selective serotonin reuptake inhibitors (SSRIs) or anti-platelet agents such as low-dose acetylsalicylic acid are at increased risk of serious GI complications (see below and section 4.5). As with other NSAIDs, the use of piroxicam in combination

with protective agents (e.g. misoprostol or proton pump inhibitors) must be considered for these at-risk patients.

Patients and physicians should remain alerted for signs and symptoms of GI ulceration and/or bleeding during piroxicam treatment. Patients should be asked to report any new or unusual abdominal symptom during treatment. If a gastrointestinal complication is suspected during treatment, piroxicam should be discontinued immediately and additional clinical evaluation and treatment should be considered.”

...[]...

...[]...

“Skin reactions

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs (see section 4.8). Evidence from observational studies suggests that piroxicam may be associated with a higher risk of serious skin reactions than other non-oxicam NSAIDs. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Piroxicam should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.”

...[]...

4.5 Interaction with other Medicinal Products and other forms of Interaction

...[]...

“As with other NSAIDs, the use of piroxicam together with acetyl-salicylic acid or concomitant use with other NSAIDs, including other piroxicam formulations, must be avoided, since data are inadequate to show that such combinations produce greater improvement than that achieved with piroxicam alone; moreover, the potential for adverse reactions is enhanced (see section 4.4). Human studies have shown that concomitant use of piroxicam and acetyl-salicylic acid reduces the plasma piroxicam concentration to about 80% of the usual value

Corticosteroids: increased risk of gastrointestinal ulceration or bleeding (see section 4.4).

Anti-coagulants: NSAIDs, including piroxicam, may enhance the effects of anti-coagulants, such as warfarin. Therefore, the use of piroxicam with concomitant anticoagulant such as warfarin should be avoided. (see section 4.3).

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see section 4.4).”

...[]...

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE PACKAGE LEAFLET FOR SYSTEMIC FORMULATIONS OF PIROXICAM CONTAINING MEDICINAL PRODUCTS

WHAT IS PIROXICAM [*Invented name*] AND WHAT IT IS USED FOR

....[]...

“Before prescribing piroxicam, your doctor will assess the benefits this medicine may give you against your risk of developing side effects. Your doctor may need to give you check-ups and will tell you how often you need to be checked, due to your taking piroxicam.

*Piroxicam [*Invented name*] is used to relieve some symptoms caused by osteoarthritis (arthrosis, degenerative joint disease), rheumatoid arthritis and ankylosing spondylitis (rheumatism of the spine), such as swelling, stiffness and joint pain. It does not cure arthritis and will help you only as long as you continue to take it.*

Your doctor will prescribe piroxicam to you only when you have had unsatisfactory relief of symptoms with other non-steroidal anti-inflammatory medicines (NSAIDs).”

....[]...

DO NOT TAKE PIROXICAM:

....[]...

- *“If you previously had a stomach or intestinal ulcer, bleeding or perforation.*
- *If you currently have stomach or intestinal ulcer, bleeding or perforation.*
- *If you have or have had a history of gastrointestinal disorders (inflammation of the stomach or intestines) that predispose to bleeding disorders such as ulcerative colitis, Crohn’s disease, gastrointestinal cancers, diverticulitis (inflamed or infected pouches/pockets in the colon).*
- *If you are taking other NSAIDs, including COX-2 selective NSAIDs and acetyl-salicylic acid, a substance present in many medicines used to relieve pain and lower fever.*
- *If you are taking anticoagulants, such as warfarin, to prevent blood clots.*
- *If you previously had a serious allergic drug reaction to piroxicam, other NSAIDs and other medications, especially serious skin reactions (regardless of severity) such as exfoliative dermatitis (intense reddening of skin, with skin peeling off in scales or layers), vesiculo-bullous reactions (Stevens-Johnson syndrome, a condition with red blistered, eroded, bloody or crusted skin) and toxic epidermal necrolysis, (a disease with blistering and peeling of the top layer of skin).”*

....[]...

- *“If any of these applies to you, you should not be given piroxicam. Tell your doctor immediately.”*

....[]...

TAKE SPECIAL CARE WITH...

....[]...

*“Take special care with [*Invented name*] and always tell your doctor before using [*Invented name*]: like all non-steroidal-anti-inflammatory drugs, [*Invented name*] can cause serious reactions in the stomach and intestines, such as pain, bleeding, ulceration, and perforation.*

You should immediately stop taking piroxicam and tell your doctor if you have stomach pain, or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained bowel movements, or vomiting blood.

You should immediately stop taking piroxicam and tell your doctor if you have any allergic reaction such as a skin rash, swelling of the face, wheezing or difficulty breathing.

If you are over 70 years old, your doctor may wish to minimise treatment duration and to see you more often while you are taking piroxicam.

If you are over 70 years old, or you are taking other medicines like corticosteroids or certain drugs for depression called selective serotonin reuptake inhibitors (SSRIs), or acetylsalicylic acid-to prevent

blood clotting, your doctor may like to prescribe you together with [Invented name] a medicine for protecting your stomach and intestines.

You should not take this medicine if you are older than 80 years.

If you have or had any medical problems or any allergies or if you are not sure as to whether you can use piroxicam tell your doctor before using this medicine.

Make sure you have told your doctor about any other medicines that you are taking, including those that you have bought without a prescription.”

....[]...

TAKING OTHER MEDICINES

....[]...

“Tell your doctor about any other medicines you are taking or took recently (in the last week) – even medicines you bought yourself without a prescription. Medicines can sometimes interfere with each other. Your doctor may limit your use of piroxicam or other medicines, or you may need to take a different medicine. It’s especially important to mention:

- if you are taking aspirin or other non-steroidal anti-inflammatory drugs for pain relief*
- if you are taking corticosteroids, which are drugs given to treat a variety of conditions such as allergies and hormone imbalances*
- if you are taking anticoagulants such as warfarin to prevent blood clots*
- if you are taking certain drugs for depression called selective serotonin re-uptake inhibitors (SSRI)*
- if you are taking any drugs, such as acetylsalicylic acid to prevent platelet clumping*

....[]...

- If any of these applies to you tell your doctor immediately.”

....[]...

HOW TO TAKE PIROXICAM

....[]...

“Always use piroxicam exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will give you a regular check-up to make sure you are taking the optimal dose of piroxicam. Your doctor will adjust your treatment to the lowest dose that best controls your symptoms. Under no circumstances should you change the dose without first speaking to your doctor.

Adults and the elderly:

The maximum daily dose is 20 milligrams of piroxicam as one single daily dose.

If you are older than 70 years your doctor may prescribe a lower daily dose and reduce the duration of treatment.

Your doctor may prescribe piroxicam with another medicine to protect your stomach and intestine for potential side effects.

Do not increase the dose

If you feel that the medicine is not very effective, always talk to your doctor.

If you forget to use piroxicam:

Take it as soon as you remember. If it is almost time for your next dose, do not take the dose you have missed, just take the next dose at the correct time. Do not double the dose.

If you have any further questions on the use of this product, ask your doctor.”

....[]...

ANNEX IV

CONDITIONS OF THE MARKETING AUTHORISATION

National Competent Authorities (NCA) shall ensure that the following conditions are fulfilled by the Marketing Authorisation Holders:

- A Direct Healthcare Professional Communication (DHPC) must be sent to all Health Care Professionals who prescribe piroxicam according to national practice. This communication should inform healthcare professionals of the risks of gastrointestinal and skin reactions associated with piroxicam and should be in line with the DHPC endorsed by the CHMP.