

## **Annex I**

**List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, and marketing authorisation holders in the Member States**

<b>Member State (in EEA)</b>	<b>Marketing authorisation holder</b>	<b>INN</b>	<b>Invented name</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
Austria	Bayer Austria GmbH Herbststrasse 6-10 1160 Wien Austria	testosterone undecanoat	Nebido 1000 mg/4 ml Injektionslösung	1000 mg/4ml	solution for injection	intramuscular use
Austria	Eli Lilly GmbH Kölblgasse 8-10 1030 Wien Austria	testosterone	Axiron 30 mg/1,5 ml Lösung zur Anwendung auf der Haut	30 mg/1,5ml	gel	cutaneous use
Austria	Laboratoires Besins International SA Rue de Bourg l'Abbè 3 75003 Paris France	testosterone	Testogel 25 mg - Gel im Beutel	25 mg	gel	cutaneous use
Austria	Laboratoires Besins International SA Rue de Bourg l'Abbè 3 75003 Paris France	testosterone	Testogel 50 mg - Gel im Beutel	50 mg	gel	cutaneous use
Austria	ProStrakan Ltd. Galabank Business Park TD1 1QH Galashiels United Kingdom	testosterone	Tostran 2% - Gel	0.02	gel	cutaneous use
Austria	Laboratoires Besins International SA Rue de Bourg l'Abbè 3 75003 Paris France	testosterone	Androgel 25 mg - Gel im Beutel	25 mg	gel	cutaneous use
Austria	Laboratoires Besins International SA Rue de Bourg l'Abbè 3 75003 Paris France	testosterone	Androgel 50 mg - Gel im Beutel	50 mg	gel	cutaneous use
Austria	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoat	Andriol Testocaps 40 mg - Kapseln	40 mg	capsule, soft	oral use

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Belgium	Besins Healthcare Avenue Louise 287 1050 Brussels Belgium	testosterone	Androgel	25 mg	gel	transdermal use
Belgium	Besins Healthcare Avenue Louise 287 1050 Brussels Belgium	testosterone	Androgel	50 mg	gel	transdermal use
Belgium	Eli Lilly Benelux S.A.-N.V. Rue du Marquis 1 1000 Brussels Belgium	testosterone	Axxeron	30 mg/1,5 ml	cutaneous solution	cutaneous use
Belgium	ProStrakan Ltd. Galabank Business Park TD1 1QH Galashiels Selkirkshire United Kingdom	testosterone	Itrogen	2%	gel	cutaneous use
Belgium	Bayer SA-NV Jan Emiel Mommaertslaan 14 1831 Machelen Belgium	testosterone undecylate	Nebido	1000 mg/4 ml	solution for injection	intramuscular use
Belgium	Aspen Pharma Trading Limited, 3016 Lake Drive Citywest Business Campus Dublin 24 Ireland	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustanon 250	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use
Belgium	Ferring SA-NV Capucienelaan 93C 9300 Aalst Belgium	testosterone	Testim	50 mg	gel	transdermal use
Belgium	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	Testocaps	40 mg	capsule, soft	oral use

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Belgium	Besins Healthcare Avenue Louise 287 1050 Brussels Belgium	testosterone	Testogel	25 mg	gel	transdermal use
Belgium	Besins Healthcare Avenue Louise 287 1050 Brussels Belgium	testosterone	Testogel	50 mg	gel	transdermal use
Bulgaria	Ferring GmbH Wittland 11 + Kiel D-24109 Germany	testosterone	Testim	50 mg	gel	transdermal use
Bulgaria	PharmaSwiss Ceska republika s.r.o. Jankovcova 1569/2c + Praha 17000 Czech Republic	testosteron decanoate testosteron isocaproate testosteron phenylpropionate testosteron propionate	Omnadren	100 mg/ml 60 mg/ml 60 mg/ml 30 mg/ml	solution for injection	intramuscular use
Bulgaria	Bayer Pharma AG Müllerstraße 178 D-13353 Berlin Germany	testosteron undecanoate	Nebido	250 mg/ml	solution for injection	intramuscular use
Bulgaria	Laboratoires Besins International rue du Bourg I 75003 Paris France	testosterone	Androgel	50 mg	gel	transdermal use
Czech Republic	BB Pharma a.s. Pod višňovkou 1662/21 140 00 Praha 4 Czech Republic	testosterone isobutyrate	Agovirin depot	25 mg/ml	suspension for injection	intramuscular use
Czech Republic	Laboratoires Besins- International rue du Bourg-I´Abbé 5 75003 Paris France	testosterone	Androgel 25 mg, gel v sáčku	10 mg/g	gel	cutaneous use

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Czech Republic	Laboratoires Besins-International rue du Bourg-l'Abbé 5 75003 Paris France	testosterone	Androgel 50 mg, gel v sáčku	10 mg/g	gel	cutaneous use
Czech Republic	BB Pharma a.s. Pod višňovkou 1662/21 140 00 Praha 4 Czech Republic	testosterone isobutyrate estradiol benzoate	Folivirin	25 mg/ml 2,5 mg/ml	suspension for injection	intramuscular use
Czech Republic	Bayer Pharma AG Müllerstrasse 178 13353 Berlin Germany	testosterone undecanoate (testosterone)	Nebido	1000 mg (631,6 mg)	solution for injection	intramuscular use
Czech Republic	Aspen Pharma Trading Limited 3016 Lake Drive Citywest Business Campus Dublin 24 Ireland	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustanon 250	30 mg/ml  60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use
Czech Republic	FERRING Pharmaceuticals CZ s.r.o. K Rybníku 475 252 42 Jesenice u Prahy Czech Republic	testosterone	Testim 50 mg gel transdermální gel	10 mg/g	gel	transdermal use
Czech Republic	N.V. Organon 6 Kloosterstraat 5340 BH Oss The Netherlands	testosterone undecanoate	Undestor	40 mg	capsule, soft	oral use
Croatia	Bayer d.o.o. Radnička cesta 80/8 Zagreb 10000 Croatia	testosteronum undecanoatum	Nebido 1000 mg/4 ml otopina za injekciju	1000 mg/4 ml	solution for injection	intramuscular use

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Croatia	Hospitalija trgovina d.o.o. Vojvodići 25, Novaki Sveta Nedelja 10431 Croatia	testosteronum	Androgel 50 mg, gel u vrećici	50 mg	gel	cutaneous use
Cyprus	Bayer Hellas ABEE 18-20 Sorou Street Marousi Athens 15125 Greece	testosterone undecanoate	Nebido	1000 mg/4ml	solution for injection	intramuscular use
Cyprus	Ferring Hellas MEPE 3 Gkyzi street Marousi 15125 Greece	testosterone	Testim	50mg	gel	cutaneous transdermal use
Cyprus	Laboratoires Besins International 3 Rue du Bourg l' Abbe Paris 75003 France	testosterone	Testogel	25 mg	gel	cutaneous transdermal use
Cyprus	Laboratoires Besins International 3 Rue du Bourg l' Abbe Paris 75003 France	testosterone	Testogel	50mg	gel	cutaneous transdermal use
Denmark	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	Andriol	40 mg	capsule, soft	oral use
Denmark	Laboratoires Besins Int., 3 rue du Bourg l'Abbé 75003 Paris France	testosterone	Androgel	25 mg/dose	gel in sachet-dose	transdermal use

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Denmark	Laboratoires Besins Int. 3 rue du Bourg l'Abbé 75003 Paris France	testosterone	Androgel	50 mg/dose	gel in sachet-dose	transdermal use
Denmark	Eli Lilly Danmark A/S Lyskær 3E, 2.tv. DK-2730 Herlev Denmark	testosterone	Axiron	2%	cutaneous solution	cutaneous use
Denmark	Bayer Pharma AG Müllerstrasse 170-178 DE-13342 Berlin Germany	testosterone	Nebido	1000 mg/dose	solution for injection	intramuscular use
Denmark	Ferring Lægemedler A/S, Kay Fiskers Plads 11 DK-2300 København S Denmark	testosterone	Testim	50 mg/dose	gel	transdermal use
Denmark	Laboratoires Besins Int. 3 rue du Bourg l'Abbé 75003 Paris France	testosterone	Testogel	50 mg/dose	gel in sachet-dose	transdermal use
Denmark	Laboratoires Besins Int. 3 rue du Bourg l'Abbé 75003 Paris France	testosterone	Testogel	25 mg/dose	gel in sachet-dose	transdermal use
Denmark	ProStrakan Ltd. Galabank Business Park TD1 1QH Galashiels United Kingdom	testosterone	Tostran	2%	gel	cutaneous use
Estonia	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	SUSTANON	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use

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Estonia	Bayer Pharma AG - 13342 Berlin Germany	testosterone	NEBIDO	250 mg/ml	solution for injection	intramuscular use
Estonia	Ferring Lääkkeet Oy PL 23, 02241 Espoo Finland	testosterone	TESTIM 50 MG GEL	50 mg	gel	transdermal use
Finland	Oy Eli Lilly Finland Ab Laajalahdentie 23 FI- 00330 Helsinki Finland	testosterone	AXIRON	30 mg/1.5 ml	cutaneous solution	transdermal use
Finland	Bayer Oy Pansiontie 47 PL 415 20101 Turku Finland	testosterone undecanoate	NEBIDO	1000 mg/4ml	solution for injection	intramuscular use
Finland	N.V. Organon PO BOX 20 5340 BH Oss The Netherlands	testosterone undecanoate	PANTESTON	40 mg	capsule, soft	oral use
Finland	Aspen Pharma Trading Limited 3016 Lake Drive Citywest Business Campus Dublin 24 Ireland	testosterone propionate testosterone phenylpropionate testosterone isocaproate, testosterone decanoate	SUSTANON"250"	30 mg/ml 60 mg/ml 60mg/ml 100 mg/ml	solution for injection	intramuscular use
Finland	Ferring Lääkkeet Oy Piispansilta 11 A PL 23 02241 Espoo Finland	testosterone	TESTIM	50 mg	gel	transdermal use



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Finland	Laboratoires Besins 3, rue du Bourg l'Abbe75003 Paris France	testosterone	TESTOGEL	25 mg/dose	gel	transdermal use
Finland	Laboratoires Besins 3, rue du Bourg l'Abbe75003 Paris France	testosterone	TESTOGEL	50 mg/dose	gel	transdermal use
Finland	ProStrakan Ltd. Galabank Business Park Galashiels, Selkirkshire TD1 1QH United Kingdom	testosterone	TOSTRAN	2%	gel	transdermal use
France	LABORATOIRES BESINS INTERNATIONAL 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	ANDROGEL 25 mg, gel en sachet-dose	25 mg/2,5 g	gel	transdermal use
France	LABORATOIRES BESINS INTERNATIONAL 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	ANDROGEL 50 mg, gel en sachet-dose	50 mg/5 g	gel	transdermal use
France	BAYER SANTE 220, avenue de la Recherche, 59120 Loos France	testosterone enantate	ANDROTARDYL 250 mg/1 ml, solution injectable intramusculaire	250 mg/ml	solution	intramuscular use
France	PROSTRAKAN Ltd Galabank Business Park TD1 1QH Galashiels United Kingdom	testosterone	FORTIGEL 2 %, gel	20 mg/g	gel	cutaneous use
France	BAYER SANTE 220, avenue de la Recherche 59120 Loos France	testosterone undecanoate	NEBIDO 1000 mg/4 ml, solution injectable	1000 mg/4 ml	Solution	intramuscular use

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France	MSD France 34, avenue Léonard de Vinci 92400 Courbevoie France	testosterone undecanoate	PANTESTONE 40 mg, capsule molle	40 mg	capsule, soft	oral use
France	LABORATOIRES BESINS INTERNATIONAL 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	TESTOGEL 25 mg, gel en sachet-dose	25 mg /2,5 g unidose	gel	transdermal use
France	LABORATOIRES BESINS INTERNATIONAL 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	TESTOGEL 50 mg, gel en sachet-dose	50 mg/5 g unidose	gel	transdermal use
France	Pierre FABRE MEDICAMENT 45, place Abel Gance, 92100 Boulogne Billancourt France	testosterone	TESTOPATCH 1,2 mg/24 heures, dispositif transdermique	15 mg/patch	patch	transdermal use
France	Pierre FABRE MEDICAMENT 45, place Abel Gance, 92100 Boulogne Billancourt France	testosterone	TESTOPATCH 1,8 mg/24 heures, dispositif transdermique	22,5 mg/patch	patch	transdermal use
France	Pierre FABRE MEDICAMENT 45, place Abel Gance 92100 Boulogne Billancourt France	testosterone	TESTOPATCH 2,4 mg/24 heures, dispositif transdermique	30 mg/patch	patch	transdermal use
France	FERRING SAS 7, rue Jean-Baptiste Clément 94250 Gentilly France	testosterone	TESTIMED 1 %, gel en récipient unidose	50 mg/5 g unidose	gel	transdermal use

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Germany	Dr. August Wolff GmbH&Co. KG Arzneimittel Sudbrackstr. 56 33611 Bielefeld Germany	testosterone	Testotop Gel 125mg	125 mg/5g	gel	cutaneous use
Germany	Dr. August Wolff GmbH&Co. KG Arzneimittel Sudbrackstr. 56 33611 Bielefeld Germany	testosterone	Testotop Gel 62,5mg	62,5 mg/2,5g	gel	cutaneous use
Germany	Eifelfango Chemisch-Pharmazeutische Werke GmbH&Co. KG Ringener Str. 45 53474 Bad Neuenahr-Ahrweiler Germany	testosterone enantate	Testosteron-Depot 250mg Eifelfango	250 mg/1ml	solution for injection	intramuscular use
Germany	Ferring Arzneimittel GmbH Fabrikstr. 7 24103 Kiel Germany	testosterone	Testim 50mg Transdermales Gel	50 mg/5g	gel	cutaneous use
Germany	GALENpharm GmbH Wittland13 24109 Kiel Germany	testosterone enantate	Testosteron-Depot GALEN 250mg	250 mg/ml	solution for injection	intramuscular use
Germany	Jenapharm GmbH&CO. KG Otto-Schott-Str.15 07745 Jena Germany	testosterone undecanoate	Nebido 1000mg Injektionslösung	250 mg/ml	solution for injection	intramuscular use
Germany	Jenapharm GmbH&CO. KG Otto-Schott-Str.15 07745 Jena Germany	testosterone enantate	Testosteron-Depot Jenapharm	250 mg/ml	solution for injection	intramuscular use

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Germany	Jenapharm GmbH&CO. KG Otto-Schott-Str.15 07745 Jena Germany	testosterone enantate	Testoviron-Depot Jenapharm	250 mg/ml	solution for injection	intramuscular use
Germany	Jenapharm GmbH&CO. KG Otto-Schott-Str.15 07745 Jena Germany	testosterone enantate	Testoviron-Depot-250	250 mg/ml	solution for injection	intramuscular use
Germany	Laboratoires Besins international 3 rue du Bourgl Abbe 75003 Paris France	testosteron	Androtop Gel 25mg	25 mg/2,5g	gel	cutaneous use
Germany	Laboratoires Besins international 3 rue du Bourgl Abbe 75003 Paris France	testosterone	Androtop Gel 50mg	50 mg/5g	gel	cutaneous use
Germany	Laboratoires Besins international 3 rue du Bourgl Abbe 75003 Paris France	testosterone	Testogel 25mg Gel im Beutel	25 mg/2,5g	gel	cutaneous use
Germany	Laboratoires Besins international 3 rue du Bourgl Abbe 75003 Paris France	testosterone	Testogel 50mg Gel im Beutel	50 mg/5g	gel	cutaneous use
Germany	Lilly Deutschland GmbH Teichweg 3 35396 Gießen Germany	testosterone	Axiron 30mg/1,5ml Lösung zur Anwendung auf der Haut	30 mg/1,5ml	solution	cutaneous use

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Germany	MSD Sharp&Dohme Gesellschaft mit beschränkter Haftung Lindenplatz 1 85540 Haar Germany	testosterone undecanoate	Andriol Testocaps	40 mg	capsule	oral use
Germany	Pierre Faber Pharma GmbH Jechtlinger Str. 13 79111 Freiburg Germany	testosterone	Testopatch 1,2mg/24h, transdermales Pflaster	15 mg	transdermal patch	transdermal use
Germany	Pierre Faber Pharma GmbH Jechtlinger Str. 13 79111 Freiburg Germany	testosterone	Testopatch 1,8mg/24h, transdermales Pflaster	22.5 mg	transdermal patch	transdermal use
Germany	Pierre Faber Pharma GmbH Jechtlinger Str. 13 79111 Freiburg Germany	testosterone	Testopatch 2,4mg/24h, transdermales Pflaster	30 mg	transdermal patch	transdermal use
Germany	ProStrakan Limited Galabank Business Park TD1 QH Galashiels United Kingdom	testosterone	Tostran 2% Gel	20 mg/g	gel	cutaneous use
Germany	Rotexmedica GmbH Arzneimittelwerk Bunsenstr.4 22946 Trittau Germany	testosterone enantate	Testosteron Depot- Rotexmedica	250 mg/ml	solution for injection	intramuscular use
Greece	Laboratoires Besins International, Paris, France 5, rue de Bourg l' Abbe 75003 Paris France	testosterone	Testogel	25 mg/sachet	gel	cutaneous use

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Greece	Laboratoires Besins International, Paris, France 5, rue de Bourg l' Abbe 75003 Paris France	testosterone	Testogel	50 mg/sachet	gel	cutaneous use
Greece	Ferring Ellas Farmakeytiki MEPE Gyzi 3 15125 Marousi Greece	testosterone	Testim	1% (w/w)	gel	cutaneous use
Greece	Prostrakan Ltd, U.K. Galabank Business Park Galashiels, TD1 1QH United Kingdom	testosterone	Tostran	2% (w/w)	gel	cutaneous use
Greece	Pierre Fabre Farmaka AE I. Mesogion 350, 15341 Ag. Paraskevi Greece	testosterone	Testopatch	1.2 mg/24h	transdermal patch	cutaneous use
Greece	Pierre Fabre Farmaka AE I. Mesogion 350 15341 Ag. Paraskevi Greece	testosterone	Testopatch	1.8 mg/24h	transdermal patch	cutaneous use
Greece	Pierre Fabre Farmaka AE I. Mesogion 350 15341 Ag. Paraskevi Greece	testosterone	Testopatch	2.4 mg/24h	transdermal patch	cutaneous use
Greece	Bayer Ellas ABEE Sorou 18-20 15125 Marousi Greece	testosterone enantate	Testoviron	250 mg/ml	solution for injection	intramuscular use
Greece	Norma Ellas AE Menandrou 54 10431 Athens Greece	testosterone enantate	Testosterone Enentate/Norma	250 mg/ml	solution for injection	intramuscular use

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Greece	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	Restandol Testocaps	40 mg	capsules, soft	oral use
Greece	Bayer Ellas ABEE Sorou 18-20 15125 Marousi Greece	testosterone undecanoate	Nebido	1000 mg/4ml	solution for injection	intramuscular use
Hungary	N.V. Organon Postbus 20 5340 BH Oss The Netherlands	testosterone undecanoate	Andriol Testocaps 40 mg lágy kapszula	40 mg	capsule, soft	oral use
Hungary	Laboratoires Besins International 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	Androgel 25 mg gél tasakban	25 mg	gel	cutaneous use
Hungary	Laboratoires Besins International 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	Androgel 50 mg gél tasakban	50 mg	gel	cutaneous use
Hungary	Bayer Pharma AG Müllerstrasse 178 D-13342 Berlin Germany	testosterone	Nebido 250 mg/ml oldatos injekció	250 mg/ml	solution for injection	intramuscular injection
Hungary	Ferring Magyarország Gyógyszerkereskedelmi Kft. Tomori u. 34. Budapest H-1138 Hungary	testosterone	Testim 50 mg transzdermális gél	50 mg	gel	cutaneous use
Hungary	ProStrakan Limited Galabank Business Park Galashiels, TD1 1QH United Kingdom	testosterone	Tostran 20 mg/g gél	20 mg/g	gel	cutaneous use

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Iceland	Laboratories BESINS INTERNATIONAL 3, rue du Bourg 1'Abbé 75003 Paris France	testosteronum	Androgel	50 mg/dosage	gel	cutaneous use
Iceland	Laboratories BESINS INTERNATIONAL 3, rue du Bourg 1'Abbé 75003 Paris France	testosteronum	Testogel	25 mg/dosage	gel	cutaneous use
Iceland	Laboratories BESINS INTERNATIONAL 3, rue du Bourg 1'Abbé 75003 Paris France	testosteronum	Testogel	50 mg/dosage	gel	cutaneous use
Iceland	Ferring Lægemedler A/S (F) Kay Fiskers Plads 11. 2300 København S Denmark	testosteronum	Testim	50 mg/dosage	gel	cutaneous use
Iceland	Bayer Pharma AG Müllerstrasse 178 13353 Berlin Germany	testosteronum undecanoat	Nebido	250 mg/ml	solution for injection	intramuscular use
Italy	Laboratorio Farmaceutico SIT Speciatilta' Igienico Terapeutiche S.R.L. Via Cavour, 70 Mede 27035 Pavia Italy	testosterone propionate	TESTOVIS	100mg/2ml	solution for injection	intramuscular use
Italy	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	SUSTANON	30 mg/ml 60 mg/ml 60mg/ml 100 mg/ml	solution for injection	intramuscular use



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Italy	BAYER S.P.A. Viale Certosa, 130 20156 Milano Italy	testosterone enanthate	TESTOVIRON	250 mg/ml	solution for injection	intramuscular use
Italy	GEYMONAT S.P.A. Via S. Anna, 2 03012 Anagni Frosinone Italy	testosterone enanthate	TESTO ENANT	100 mg/ml	solution for injection	intramuscular use
Italy	GEYMONAT S.P.A., Via S. Anna, 2 03012 Anagni Frosinone Italy	testosterone enanthate	TESTO ENANT	250 mg/2ml	solution for injection	intramuscular use
Italy	BAYER S.P.A., Viale Certosa, 130 20156 Milano Italy	testosterone undecanoate	NEBID	1000 mg/4ml	solution for injection	intramuscular use
Italy	MSD ITALIA S.R.L. Via Vitorchiano 151 00189 Roma Italy	testosterone undecanoate	ANDRIOL	40 mg	capsules	oral use
Ireland	Laboratoires BESINS INTERNATIONAL, 3 Rue du Bourg l'Abbé 75003 Paris France	testosterone	Androgel 25 mg, gel in sachet	25 mg	gel	cutaneous use
Ireland	Laboratoires BESINS INTERNATIONAL 3 Rue du Bourg l'Abbé 75003 Paris France	testosterone	Androgel 50 mg, gel in sachet	50 mg	gel	cutaneous use

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Ireland	Laboratoires BESINS INTERNATIONAL 3 Rue du Bourg l'Abbé 75003 Paris France	testosterone	Testogel 25 mg, gel in sachet	25 mg	gel	cutaneous use
Ireland	Laboratoires BESINS INTERNATIONAL 3 Rue du Bourg l'Abbé 75003 PARIS France	testosterone	Testogel 50 mg, gel in sachet	50 mg	gel	cutaneous use
Ireland	ProStrakan Ltd. Galabank Business Park Galashiels TD1 1QH United Kingdom	testosterone	Tostran 2% Gel	2% w/w (20mg testosterone per 1g gel)	gel	cutaneous use
Ireland	Ferring Ireland Ltd United Drug House Magna Drive Magna Business Park Citywest Road Dublin 24 Ireland	testosterone	Testim 50mg Gel	50 mg	gel	cutaneous use
Ireland	Organon (Ireland) Limited PO Box 2857, Drynam Road, Swords Co. Dublin Ireland	testosterone undecanoate	Restandol Testocaps	40 mg	capsules, soft	oral use
Ireland	Bayer Limited The Atrium Blackthorn Road Dublin 18 Ireland	testosterone undecanoate	Nebido 1000 mg/4ml, solution for injection	250 mg/ml	solution for Injection	intramuscular
Latvia	Ferring Laakkeet Oy Piispansilta 11 A 02230 Espoo Finland	testosterone	Testim 50 mg transdermal gel	50 mg	gel	transdermal use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Latvia	PharmaSwiss Česká republika s.r.o. Jankovcova 1569/2c 170 00 Prague 7 Czech Republic	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Omnadren 250 mg/ml solution for injection	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use
Latvia	Laboratoires BESINS INTERNATIONAL 3, rue duBourg l'Abbe 75003 Paris France	testosterone	Androgel 25 mg gel in sachet	25 mg	gel in sachet	cutaneous use
Latvia	Laboratoires BESINS INTERNATIONAL 3, rue duBourg l'Abbe 75003 PARIS France	testosterone	Androgel 50 mg gel in sachet	50 mg	gel in sachet	cutaneous use
Latvia	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustanon 250 mg/ml solution for injection	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use
Latvia	Bayer Pharma AG D-13342 Berlin Germany	testosterone undecanoate	Nebido 1000 mg/4 ml solution for injection	1000 mg/4 ml	solution for injection	intramuscular use
Lithuania	Bayer Pharma AG Mullerstrasse 178 D-13342 Berlin Germany	testosterone undecanoate	Nebido	1000 mg/4 ml	solution for injection	intramuscular use
Lithuania	N.V. ORGANON P.O. Box 20 5340 BH Oss The Netherlands	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustanon	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use

<b>Member State (in EEA)</b>	<b>Marketing authorisation holder</b>	<b>INN</b>	<b>Invented name</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
Lithuania	Ferring Lääkkeet Oy PL 23 02241 Espoo Finland	testosterone	Testim	50 mg	gel	transdermal use
Luxembourg	Besins International S.A. 3, rue du Bourg l'Abbe 75003 Paris France	testosterone	Androgel	25 mg/2,5 g	gel	cutaneous use
Luxembourg	Besins International S.A. 3, rue du Bourg l'Abbe 75003 Paris France	testosterone	Androgel	50 mg/5 g	gel	cutaneous use
Luxembourg	Eli Lilly Benelux S.A. -N.V 1, rue du Marquis 1000 Bruxelles Belgium	testosterone	Axxeron	30 mg/1,5 ml	transdermal spray, solution	cutaneous use
Luxembourg	Prostrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	testosterone	Itrogen	2 g/100 g	gel	cutaneous use
Luxembourg	Bayer S.A. -N.V. 14, J.E.Mommaerstlaan 1831 Diegem (Machelen) Belgium	testosterone undecanoate	Nebido	250 mg/ml	solution for injection	intramuscular use
Luxembourg	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustanon	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use

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Luxembourg	Ferring S.A. 93C, Capucienenlaan 9300 Aalst Belgium	testosterone	Testim	50 mg/5 g	gel	cutaneous use
Luxembourg	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	Testocaps	40 mg	capsule, soft	oral use
Luxembourg	Besins International S.A. 3, rue du Bourg l'Abbe 75003 Paris France	testosterone	Testogel	25 mg/2,5 g	gel	cutaneous use
Luxembourg	Besins International S.A. 3, rue du Bourg l'Abbe 75003 Paris France	testosterone	Testogel	50 mg/5 g	gel	cutaneous use
Malta	Bayer plc Bayer House Strawberry Hill Newbury Berkshire RG14 1JA United Kingdom	testosterone undecanoate	Nebido	250 mg/ml	solution for injection	intramuscular use
Malta	Ferring Pharmaceuticals Limited Drayton Hall Church Road West Drayton UB7 7PS United Kingdom	testosterone	Testim 50mg Transdermal Gel	50 mg/5g	gel	transdermal use
The Netherlands	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosteronundecanoaat	Andriol Testocaps, 40 mg capsules	40,0 mg	capsule, soft	oral use

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The Netherlands	Laboratoires Besins International 3, rue du Bourg l'Abbé Paris 75003 France	testosteron	Androgel 25 mg, gel in sachet	25,0 mg/sachet	gel	cutaneous use
The Netherlands	Laboratoires Besins International 3, rue du Bourg l'Abbé Paris 75003 France	testosteron	Androgel 50 mg, gel in sachet	50 mg/sachet	gel	cutaneous use
The Netherlands	Bayer B.V. Energieweg 1 3641 RT Mijdrecht The Netherlands	testosteronundecanoaat	Nebido 1000 mg/4 ml, oplossing voor injectie	250,0 mg/ml	solution for injection	intramuscular use
The Netherlands	Aspen Pharma Trading Limited 3016 Lake Drive Citywest Business Campus Dublin 24 Ireland	testosteron: testosterone isocaproate testosteron phenylpropionate testosterone propionate	Sustanon 100 mg/ml, oplossing voor injectie	74,0 mg/ml: 40 mg/ml 40 mg/ml 20 mg/ml	solution for injection	intramuscular use
The Netherlands	Aspen Pharma Trading Limited 3016 Lake Drive Citywest Business Campus Dublin 24 Ireland	testosteron: testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustanon 250 mg/ml, oplossing voor injectie	176,1 mg/ml:-30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use
The Netherlands	Ferring B.V. Polarisavenue 130 2132 JX Hoofddorp The Netherlands	testosteron	Testim 50 mg gel, gel 50 mg/tube	50 mg	gel	cutaneous use

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The Netherlands	Laboratoires Besins International 3, rue du Bourg l'Abbé Paris 75003 France	testosteron	Testogel 25 mg, gel in sachet	25 mg	gel	cutaneous use
The Netherlands	Laboratoires Besins International 3, rue du Bourg l'Abbé Paris 75003 France	testosteron	Testogel 50 mg, gel in sachet	50 mg	gel	cutaneous use
The Netherlands	ProStrakan Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	testosteron	Tostran 2% gel, gel 0,02 g/g	0,02 g/g	gel	cutaneous use
Norway	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	Andriol	40 mg	capsule, soft	oral use
Norway	Eli Lilly Norge AS P.B. 6090 Etterstad N-0601 Oslo Norway	testosterone	Axiron	20mg/ml	cutaneous solution	transdermal use
Norway	Bayer Pharma AG, Müllerstrasse 178 03353 Berlin Germany	testosterone undecanoate	Nebido	1000 mg/4ml	solution for injection	parenteral use
Norway	Ferring Legemidler AS Nydalsveien 36B 0484 Oslo Norway	testosterone	Testim	50 mg/5g	gel	transdermal use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Norway	Laboratoires Besins International 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	Testogel	25 mg/2,5g	gel	transdermal use
Norway	Laboratoires Besins International 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	Testogel	50 mg/5g	gel	transdermal use
Norway	ProStrakan Ltd Galabank Business Park Galashiels, TD1 1PR United Kingdom	testosterone	Tostran	2%	gel	transdermal use
Poland	Laboratoires Besins International 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	Androtop	25 mg/2,5 g	gel	cutaneous use
Poland	Bayer Pharma AG Müllerstrasse 178 13353 Berlin Germany	testosterone undecanoate	Nebido	1000 mg/4 ml	solution for injection intramuscular	intramuscular use
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c + Prahá 17000 Czech Republic	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Omnadren 250	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use
Poland	Ferring GmbH Wittland 11, D-24109 Kiel Germany	testosterone	Testim	50 mg	gel	cutaneous use



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Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c + Praha 17000 Czech Republic	testosterone enantane	Testosteronum prolongatum Jelfa	100 mg/ml	solution for injection	intramuscular use
Poland	ProStrakan Limited Galabank Business Park TD1 QH Galashiels United Kingdom	testosterone	Tostran 2% żel	2%	gel	cutaneous use
Poland	N.V. ORGANON Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	Undestor Testocaps	40 mg	capsule	oral use
Portugal	Merck Sharp & Dohme, Lda. Quinta da Fonte - Edifício Vasco da Gama, 19 - Porto Salvo 2770-192 Paço d' Arcos Portugal	testosterone undecanoate	Andriol - T	40 mg	capsule, soft	oral use
Portugal	Besins International, S.A. 5, Rue du Bourg l'Abbé F-75003 Paris France	testosterone	Androgel	25 mg/2.5 g	gel	cutaneous use
Portugal	Besins International, S.A. 5, Rue du Bourg l'Abbé F-75003 Paris France	testosterone	Androgel	50 mg/5 g	gel	cutaneous use
Portugal	Bayer Portugal, S.A. Rua Quinta do Pinheiro, 5 2794-003 Carnaxide Portugal	testosterone undecanoate	Nebido	1000 mg/4 ml	solution for injection	intramuscular use

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Portugal	Aspen Pharma Trading Limited.3016 Lake Drive. Citywest business campus. Dublin 24. Ireland	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustenon	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use
Portugal	Ferring Portuguesa - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Rua Alexandre Herculano - Edifício 1, Piso 6 2795-240 Linda-a-Velha Portugal	testosterone	Testim	50 mg/5 g	gel	transdermal use
Portugal	Besins International, S.A. 5, Rue du Bourg l'Abbé F-75003 Paris France	testosterone	Testogel	25 mg/2.5 g	gel	cutaneous use
Portugal	Besins International, S.A. 5, Rue du Bourg l'Abbé F-75003 Paris France	testosterone	Testogel	50 mg/5 g	gel	cutaneous use
Portugal	Pierre Fabre Médicament Portugal, Lda. Rua Rodrigo da Fonseca 178 - 2º Esq 1099-067 Lisboa Portugal	testosterone	Testopatch	1.2 mg/24 h	transdermal patch	transdermal use
Portugal	Pierre Fabre Médicament Portugal, Lda. Rua Rodrigo da Fonseca 178 - 2º Esq 1099-067 Lisboa Portugal	testosterone	Testopatch	1.8 mg/24 h	transdermal patch	transdermal use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Pierre Fabre Médicament Portugal, Lda. Rua Rodrigo da Fonseca 178 - 2º Esq 1099-067 Lisboa Portugal	testosterone	Testopatch	2.4 mg/24 h	transdermal patch	transdermal use
Portugal	Bayer Portugal, S.A. Rua Quinta do Pinheiro, 5 2794-003 Carnaxide Portugal	testosterone enantate	Testoviron Depot	250 mg/1 ml	solution for injection	intramuscular use
Portugal	ProStrakan Limited Galabank Business Park TD1 1QH Galashiels United Kingdom	testosterone	Tostran	20 mg/g	gel	cutaneous use
Romania	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	UNDESTOR TESTOCAPS 40 mg, capsule moi	40 mg	capsules soft	Oral use
Romania	BAYER PHARMA AG Müllerstraße 178 13353 Berlin Germany	testosterone undecanoat	NEBIDO 1000 mg/4 ml	1000 mg/4 ml	solution for injection	intramuscular use
Romania	LABORATOIRES BESINS INTERNATIONAL 3, rue de Bourg L'Abbé 75003 Paris France	testosterone	ANDROGEL 50 mg	50 mg/5 g	gel	cutaneous use
Romania	Ferring GmbH Wittland 11, D-24109 Kiel Germany	testosterone	TESTIM 50 mg	50 mg/5 g	gel	cutaneous use
Slovak Republic	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	Undestor Testocaps 40 mg	40 mg	capsule, soft	oral use

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Slovak Republic	Bayer Pharma AG Müllerstr. 178 13353 Berlin Germany	testosterone	Nebido 1000 mg/4 ml injekčný roztok	250 mg/ml	solution for injection	intramuscular use
Slovak Republic	Aspen Pharma Trading Limited 3016 Lake Drive Citywest Business Campus Dublin 24 Ireland	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustanon 250	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use
Slovak Republic	BB Pharma a.s. Pod Višňovkou 1662/21 14000 Praha 4 Czech Republic	testosterone	AGOVIRIN DEPOT	5 mg/2 ml	suspension for injection	intramuscular use
Slovak Republic	BB Pharma a.s. Pod Višňovkou 1662/21 14000 Praha 4 Czech Republic	estradiol/testosterone	FOLIVIRIN	2,5 mg/25 mg/ ml	suspension for injection	intramuscular use
Slovak Republic	Ferring-Léčiva, a.s. K Rybníku 475 252 42 Jesenice u Prahy Czech Republic	testosterone	Testim 50 mg gél	50 mg/5 g	transdermal gel	transdermal use
Slovenia	Ferring GmbH Wittland 11 24109 Kiel Germany	testosterone	TESTIM 50 mg transdermalni gel	50 mg	transdermal gel	transdermal use
Slovenia	Bayer Pharma AG 13342 Berlin Germany	testosterone	Nebido 1000 mg/4 ml raztopina za injiciranje	1000 mg/4 ml	Solution for injection	intramuscular use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovenia	Laboratoires BESINS INTERNATIONAL 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	Androtop 50 mg gel v blazinici	50 mg	gel in sachet	transdermal use
Slovenia	Laboratoires BESINS INTERNATIONAL 3, rue du Bourg l'Abbé 75003 Paris France	testosterone	Androtop 25 mg gel v blazinici	25 mg	gel in sachet	transdermal use
Spain	DESMA LABORATORIO FARMACÉUTICO, S.L. Cuatro Amigos, 7 Escalera 2, 1ºD 28029 Madrid Spain	testosterone propionate	TESTEX	25 mg/ml	solution for injection	intramuscular use
Spain	DESMA LABORATORIO FARMACÉUTICO, S.L. Cuatro Amigos, 7 Escalera 2, 1ºD 28029 Madrid Spain	testosterone propionate	TESTEX PROLONGATUM 100	100 mg/2 ml	solution for injection	intramuscular use
Spain	DESMA LABORATORIO FARMACÉUTICO, S.L. Cuatro Amigos, 7 Escalera 2, 1ºD 28029 Madrid Spain	testosterone propionate	TESTEX PROLONGATUM 250	250 mg/2 ml	solution for injection	intramuscular use
Spain	BESINS INTERNACIONAL 3, Rue du Bourg l'Abbe 75003 Paris France	testosterone	TESTOGEL 50 mg gel en sobres	1 g/100 g	gel	cutaneous use

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Spain	FERRING, S.A.U. Gobelas, 11 Urbanización La Florida 28023 Madrid Spain	testosterone	TESTIM 50 mg gel	1 g/100 g	gel	cutaneous use
Spain	BAYER HISPANIA, S.L. Avda. Baix Llobregat 3 y 5 08970 Sant Joan Despi Barcelona Spain	testosterone undecanoate	REANDRON 1000 mg/4 ml solución inyectable	1000 mg/4 ml	solution for injection	intramuscular use
Spain	PROSTRAKAN LIMITED Galabank Bussines Park Galashield TD1 1QH United Kingdom	testosterone	ITNOGEN 2% gel	2 g/100 g	gel	cutaneous use
Spain	PIERRE FABRE IBERICA S.A. Ramón Trías Fargas, 7-11 08005 Barcelona Spain	testosterone	TESTOPATCH 1,2 mg/24 h parche transdérmico	1.2 mg/24 h	transdermal patch	cutaneous use
Spain	PIERRE FABRE IBERICA S.A. Ramón Trías Fargas, 7-11 08005 Barcelona Spain	testosterone	TESTOPATCH 1,8 mg/24 h parche transdérmico	1.8 mg/24 h	transdermal patch	cutaneous use
Spain	PIERRE FABRE IBERICA S.A. Ramón Trías Fargas, 7-11 08005 Barcelona Spain	testosterone	TESTOPATCH 2,4 mg/24 h parche transdérmico	2.4 mg/24 h	transdermal patch	cutaneous use
Sweden	N.V. Organon Kloosterstraat 6 5349 AB Oss The Netherlands	testosterone undecanoate	Undestor® Testocaps®	40 mg	capsule, soft	oral use

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Sweden	Laboratoires Besins International 3, rue du Bourg l' Abbé FR-75003 Paris France	testosterone	Testogel	25 mg	gel in sachet	cutaneous and transdermal preparations
Sweden	Laboratoires Besins International, 3, rue du Bourg l' Abbé FR-75003 Paris France	testosterone	Testogel	50 mg	gel in sachet	cutaneous and transdermal preparations
Sweden	ProStrakan Ltd, Galabank Business Park Galashiels TD1 1QH United kingdom	testosterone	Tostrex	2%	gel	cutaneous and transdermal preparations
Sweden	Ferring Läkemedel AB Box 4041 203 11 Malmö Sweden	testosterone	Testim	50 mg	gel	cutaneous and transdermal preparations
Sweden	Bayer Pharma AG DE-13342 Berlin Germany	testosterone	Nebido	1000 mg/4 ml	solution for injection	parenteral use
Sweden	Eli Lilly Sweden AB Box 721 169 27 Solna Sweden	testosterone	Axiron	30 mg/1.5 ml	cutaneous solution	cutaneous and transdermal preparations
United Kingdom	Alliance Pharmaceuticals Limited Avonbridge House Bath Road, Chippenham Wiltshire SN15 2BB United Kingdom	testosterone enantate	Testosterone Enantate Ampoules	250 mg/ml	solution for injection	intramuscular use

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United Kingdom	Bayer Plc Bayer House Strawberry Hill, Newbury RG14 1JA United Kingdom	testosterone undecanoate	Nebido 1000mg/4ml, solution for injection	1000 mg/4ml	solution for injection	intramuscular use
United Kingdom	DHP Healthcare Limited 26 Pickering Street Maidstone, Kent ME15 9RS United Kingdom	testosterone propionate	Virormone (100mg/2ml)	100 mg/2ml	solution for injection	intramuscular use
United Kingdom	Ferring Pharmaceuticals Limited Drayton Hall, Church Road West Drayton UB7 7PS United Kingdom	testosterone	Testim 50mg Transdermal Gel	50 mg	gel	transdermal use
United Kingdom	Laboratoires Besins International 5 Rue du Bourg L'Abbe Paris F-75003 France	testosterone	Testogel 50mg. Gel in Sachet	50 mg	gel	cutaneous use
United Kingdom	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	testosterone undecanoate	Restandol 40mg	40 mg	capsule	oral use
United Kingdom	Aspen Pharma Trading Limited 3016 Lake Drive Citywest Business Campus Dublin 24 Ireland	testosterone propionate testosterone phenylpropionate testosterone isocaproate testosterone decanoate	Sustanon 250	30 mg/ml 60 mg/ml 60 mg/ml 100 mg/ml	solution for injection	intramuscular use



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United Kingdom	Prostrakan Limited 3 Galabank Business Park Queen Street, Galashiels TD1 1QH United Kingdom	testosterone	Tostran 2% Gel	2% w/w	gel	cutaneous use