



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2016
EMA/411814/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: testosterone (topical use)

Procedure no.: PSUSA/00002908/201512



Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Androgel		BE248437	Besins Healthcare Benelux	Belgium
Androgel	NL/H/3240/001	BE 489351 \$ BE489351	Besins Healthcare	Belgium
Androgel	NL/H/3240/001	OGYI-T-20015/03 \$ OGYI-T-20015/04 \$ OGYI-T-20015/05 \$ OGYI-T-20015/06	Besins Healthcare	Hungary
Androgel	NL/H/3240/002	035865144/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865157/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865169/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865171/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865183/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865195/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865207/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865219/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865221/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	05-0630	Laboratoires Besins International	Latvia
Androgel	NL/H/3240/002	1-24745	Besins Healthcare	Austria
Androgel	NL/H/3240/002	20060486	Laboratoires Besins International	Bulgaria
Androgel	NL/H/3240/002	32043	Laboratoires Besins International	Greece
Androgel	NL/H/3240/002	33563	Laboratoires Besins International	Denmark
Androgel	NL/H/3240/002	357 538-5	Laboratoires Besins International	France

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Androgel	NL/H/3240/002	357 635-0	Laboratoires Besins International	France
Androgel	NL/H/3240/002	4152385	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4152484	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4152583	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4152682	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4152781	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4152880	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4152989	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4153086	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4153185	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4153284	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	4153383	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/002	563 144-9	Laboratoires Besins International	France
Androgel	NL/H/3240/002	563 548-2	Laboratoires Besins International	France
Androgel	NL/H/3240/002	6549/2006/01	Laboratoires Besins International	Romania
Androgel	NL/H/3240/002	BE248437	Besins Healthcare Benelux	Belgium
Androgel	NL/H/3240/002	LT/1/06/0589/012	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/013	Laboratoires Besins International	Lithuania

Product Name (in authorisation country)	MRP /DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Androgel	NL/H/3240/002	LT/1/06/0589/014	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/014	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/015	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/016	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/017	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/019	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/020	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/021	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	LT/1/06/0589/022	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/002	OGYI-T-20 015/02	Laboratoires Besins International	Hungary
Androgel	NL/H/3240/002	PA1054/001/002	Laboratoires Besins International	Ireland
Androgel	NL/H/3240/002	RVG 27741	Laboratoires Besins International	Netherlands
Androgel	NL/H/3240/002	035865120/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/002	035865132/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865017/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865029/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865031/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865043/M	Laboratoires Besins International	Italy

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Androgel	NL/H/3240/003	035865056/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865068/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865070/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865082/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865094/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865106/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	035865118/M	Laboratoires Besins International	Italy
Androgel	NL/H/3240/003	05-0629	Laboratoires Besins International	Latvia
Androgel	NL/H/3240/003	1-24744	Besins Healthcare	Austria
Androgel	NL/H/3240/003	32042	Laboratoires Besins International	Greece
Androgel	NL/H/3240/003	33561	Laboratoires Besins International	Denmark
Androgel	NL/H/3240/003	357 536-2	Laboratoires Besins International	France
Androgel	NL/H/3240/003	357 634-4	Laboratoires Besins International	France
Androgel	NL/H/3240/003	4151288	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4151387	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4151486	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4151585	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4151684	Laboratoires Besins International	Portugal

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Androgel	NL/H/3240/003	4151783	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4151882	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4151981	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4152088	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4152187	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	4152286	Laboratoires Besins International	Portugal
Androgel	NL/H/3240/003	56/604/05-C	Laboratoires Besins International	Czech Republic
Androgel	NL/H/3240/003	563 143-2	Laboratoires Besins International	France
Androgel	NL/H/3240/003	563 547-6	Laboratoires Besins International	France
Androgel	NL/H/3240/003	BE248421	Besins Healthcare	Belgium
Androgel	NL/H/3240/003	BE248421	Besins Healthcare	Belgium
Androgel	NL/H/3240/003	LT/1/06/0589/001	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/002	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/002	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/003	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/005	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/006	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/007	Laboratoires Besins International	Lithuania

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Androgel	NL/H/3240/003	LT/1/06/0589/008	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/009	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/010	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	LT/1/06/0589/011	Laboratoires Besins International	Lithuania
Androgel	NL/H/3240/003	OGYI-T-20015/01	Laboratoires Besins International	Hungary
Androgel	NL/H/3240/003	PA 1054/001/001	Laboratoires Besins International	Ireland
Androgel	NL/H/3240/003	RVG 27740	Laboratoires Besins International	Netherlands
Androgel	NL/H/3240/002	56/605/05-C	Laboratoires Besins International	Czech Republic
Androtop	FR/H/0204/001	5363-I-1084/08	Laboratoires Besins International	Slovenia
Androtop	FR/H/0204/001	5363-I-1085/08	Laboratoires Besins International	Slovenia
Androtop	FR/H/0204/001 \$ FR/H/0204/002	54560.00.00 \$ 54561.00.00	Dr. Kade / Besins Pharma Gmbh	Germany
Androtop	NL/H/3240/002	12267	Laboratoires Besins International	Poland
Androtop	NL/H/3240/003	12266	Laboratoires Besins International	Poland
Androtopic	FR/H/0203/001	17269	Laboratoires Besins International	Finland
Androtopic	FR/H/203/02	17270	Laboratoires Besins International	Finland
Axiron	DE/H/3320/001	11-8312	Eli Lilly Norge A.S.	Norway
Axiron	DE/H/3320/001	135180	Eli Lilly Ges. M.B.H	Austria
Axiron	DE/H/3320/001	135180	Eli Lilly Ges. M.B.H	Liechtenstein
Axiron	DE/H/3320/001	29760	Oy Eli Lilly Finland Ab	Finland

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Axiron	DE/H/3320/001	46106	Eli Lilly Sweden Ab	Sweden
Axiron	DE/H/3320/001	48797	Eli Lilly Danmark A/S	Denmark
Axiron	DE/H/3320/001	84978.00.00	Lilly Deutschland Gmbh	Germany
Axxeron	DE/H/3320/001	041224015 \$ 041224027	Eli Lilly Italia S.P.A.	Italy
Axxeron	DE/H/3320/001	2014040013	S.A. Eli Lilly Benelux N.V.	Luxembourg
Axxeron	DE/H/3320/001	BE444175	S.A. Eli Lilly Benelux N.V.	Belgium
Testim	UK/H/0645/001	021960	Ferring Hellas Mepe	Cyprus
Testim	UK/H/0645/001	036774014 \$ 036774026 \$ 036774038 \$ 036774040	Ferring S.P.A.	Italy
Testim	UK/H/0645/001	04-2531	Ferring Legemidler As	Norway
Testim	UK/H/0645/001	12-0264	Ferring Gmbh	Latvia
Testim	UK/H/0645/001	19237	Ferring Lääkkeet Oy	Finland
Testim	UK/H/0645/001	20535	Ferring Gmbh	Poland
Testim	UK/H/0645/001	20719	Ferring Läkemedel Ab	Sweden
Testim	UK/H/0645/001	36437	Ferring Lægemedler A/S	Denmark
Testim	UK/H/0645/001	5149/2012/01 \$ 5149/2012/02 \$ 5149/2012/03 \$ 5149/2012/04	Ferring Gmbh	Romania
Testim	UK/H/0645/001	56/0505/12-S	Ferring Léciva A.S.	Slovakia
Testim	UK/H/0645/001	56/611/12-C	Ferring Pharmaceuticals Cz S.R.O.	Czech Republic
Testim	UK/H/0645/001	59857.00.00	Ferring Arzneimittel Gmbh	Germany
Testim	UK/H/0645/001	66.461	Ferring S.A.U.	Spain
Testim	UK/H/0645/001	792212	Ferring Gmbh	Estonia

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Testim	UK/H/0645/001	9222	Ferring Hellas Mepe	Greece
Testim	UK/H/0645/001	IS/1/04/020/01	Ferring Lægemedler A/S	Iceland
Testim	UK/H/0645/001	MA832/00901	Ferring Pharmaceuticals Ltd.	Malta
Testim	UK/H/0645/001	OGYI-T-22254/01	Ferring Magyarország Gyógyszerkereskedelmi Kft.	Hungary
Testim	UK/H/0645/001	PA 1009/23/1	Ferring Ireland Ltd.	Ireland
Testim	UK/H/0645/001	PL 03194/0105	Ferring Pharmaceuticals Ltd.	United Kingdom
Testim	UK/H/0645/001	RVG 30653	Ferring B.V.	Netherlands
Testim	UK/H/0645/001 \$ UK/H/645/001	LT/1/13/3203/001 \$ LT/1/13/3203/002 \$ LT/1/13/3203/003 \$ LT/1/13/3203/004	Ferring Gmbh	Lithuania
Testim	UK/H/645/001	5149786 \$ 5149885 \$ 5149984	Ferring Portuguesa – Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Portugal
Testogel	FR/H/0204/001	02- 1064	Laboratoires Besins International	Norway
Testogel	FR/H/0204/001	035864127/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864139/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864141/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864154/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864166/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864178/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864180/M	Laboratoires Besins	Italy

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			International	
Testogel	FR/H/0204/001	035864192/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864204/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864216/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	035864228/M	Laboratoires Besins International	Italy
Testogel	FR/H/0204/001	1315-01	Laboratoires Besins International	Cyprus
Testogel	FR/H/0204/001	17272	Laboratoires Besins International	Finland
Testogel	FR/H/0204/001	18359	Laboratoires Besins International	Sweden
Testogel	FR/H/0204/001	32045	Laboratoires Besins International	Greece
Testogel	FR/H/0204/001	33565	Laboratoires Besins International	Denmark
Testogel	FR/H/0204/001	357 543-9	Laboratoires Besins International	France
Testogel	FR/H/0204/001	357 856-7	Laboratoires Besins International	France
Testogel	FR/H/0204/001	4154589	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4154688	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4154787	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4154886	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4154985	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4155081	Laboratoires Besins International	Portugal

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Testogel	FR/H/0204/001	4155180	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4155289	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4155388	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4155487	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	4155586	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/001	563 146-1	Laboratoires Besins International	France
Testogel	FR/H/0204/001	563 550-7	Laboratoires Besins International	France
Testogel	FR/H/0204/001	65.016	Laboratoires Besins International	Spain
Testogel	FR/H/0204/001	BE248412	Laboratoires Besins International	Belgium
Testogel	FR/H/0204/001	IS/1/02/023/02	Laboratoires Besins International	Iceland
Testogel	FR/H/0204/001	PA 1054/2/2	Laboratoires Besins International	Ireland
Testogel	FR/H/0204/001	PL 16468/0005	Laboratoires Besins International	United Kingdom
Testogel	FR/H/0204/001	RVG 27724	Laboratoires Besins International	Netherlands
Testogel	FR/H/0204/001 \$ FR/H/0204/002	1-24746 \$ 1-24747	Laboratoires Besins International	Austria
Testogel	FR/H/0204/001 \$ FR/H/0204/002	54562.00.00 \$ 54563.00.00	Dr. Kade / Besins Pharma GmbH	Germany
Testogel	FR/H/0204/002	02-1063	Laboratoires Besins International	Norway
Testogel	FR/H/0204/002	0630/02/07/0051	Laboratoires Besins International	Luxembourg
Testogel	FR/H/0204/002	1315-02	Laboratoires Besins International	Cyprus

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Testogel	FR/H/0204/002	17271	Laboratoires Besins International	Finland
Testogel	FR/H/0204/002	18358	Laboratoires Besins International	Sweden
Testogel	FR/H/0204/002	32044	Laboratoires Besins International	Greece
Testogel	FR/H/0204/002	33564	Laboratoires Besins International	Denmark
Testogel	FR/H/0204/002	4153482	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4153581	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4153680	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4153789	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4153888	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4153987	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4154084	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4154183	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4154282	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4154381	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	4154480	Laboratoires Besins International	Portugal
Testogel	FR/H/0204/002	BE248403	Laboratoires Besins International	Belgium
Testogel	FR/H/0204/002	BE248403	Laboratoires Besins International	Belgium
Testogel	FR/H/0204/002	IS/1/02/023/01	Laboratoires Besins International	Iceland

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Testogel	FR/H/0204/002	PA 1054/2/1	Laboratoires Besins International	Ireland
Testogel	FR/H/0204/002	RVG 27723	Laboratoires Besins International	Netherlands
Testogel	FR/H/0204/002	357 541-6	Laboratoires Besins International	France
Testogel	FR/H/0204/002	357 855-0	Laboratoires Besins International	France
Testogel	FR/H/0204/002	563 145-5	Laboratoires Besins International	France
Testogel	FR/H/0204/002	563 549-9	Laboratoires Besins International	France
Testogel	NL/H/3240/001	PA1054/002/004	Besins Healthcare	Ireland
Testogel	NL/H/3240/001	PL 28397/0007	Besins Healthcare	United Kingdom
Testogel	FR/H/0204/001	0630/02/07/0052	Laboratoires Besins International	Luxembourg
Testogel	FR/H/0204/001	BE248412	Laboratoires Besins International	Belgium
Testopatch	FR/H/0297/001 \$ FR/H/0297/002 \$ FR/H/0297/003	87973/18-12-2012 \$ 87974/18-12-2012 \$ 87975/18-12-2012	Pharma Fabre / Greece	Greece
Testosterone Ferring	UK/H/0645/001	266 554-8 OU 34009 266 554 8 8 \$ 266 555-4 OU 34009 266 555 4 9 \$ 266 556-0 OU 34009 266 556 0 0 \$ 583 419-3 OU 34009 583 419 3 9	Ferring S.A.S.	France
Testosterone Lilly	DE/H/3320/001	NL41155	Lilly France	France
Testotop		63540.00.00 \$ 63541.00.00	Dr. August Wolff GmbH & Co. Kg Arzneimittel	Germany
тестим	UK/H/0645/001	20120484	Ferring GmbH	Bulgaria