



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: testosterone (topical use)

Procedure no.: PSUSA/00002908/201812



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/3240/001	54384	BESINS HEALTHCARE	DK
Androgel 16,2 mg/g gel	NL/H/3240/001	8864/2016/01	BESINS HEALTHCARE	RO
Androgel 16,2 mg/g gel	NL/H/3240/001	8864/2016/02	BESINS HEALTHCARE	RO
Androgel 16,2 mg/g gel	NL/H/3240/001	8864/2016/03	BESINS HEALTHCARE	RO
Androgel 16,2 mg/g gel	NL/H/3240/001	8864/2016/04	BESINS HEALTHCARE	RO
Androgel 16,2 mg/g gel	NL/H/3240/001	56/146/16-C	BESINS HEALTHCARE	CZ

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 16,2 mg/g gél	NL/H/3240/001	OGYI-T-20015/04	BESINS HEALTHCARE	HU
ANDROGEL 16,2 mg/g gél	NL/H/3240/001	OGYI-T-20015/05	BESINS HEALTHCARE	HU
ANDROGEL 16,2 mg/g gél	NL/H/3240/001	OGYI-T-20015/06	BESINS HEALTHCARE	HU
ANDROGEL 16,2 mg/g gél	NL/H/3240/001	OGYI-T-20015/03	BESINS HEALTHCARE	HU
ANDROGEL 16,2 mg/g hlaup	NL/H/3240/001	IS/1/16/027/01	BESINS HEALTHCARE	IS
ANDROGEL 16,2 mg/g, gel	NL/H/3240/001	BE 489351	BESINS HEALTHCARE	BE

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 16,2 mg/g, gel	NL/H/3240/001	RVG 115746	BESINS HEALTHCARE	NL
ANDROGEL 16,2 mg/g, gel	NL/H/3240/001	34009 300 537 0 6	BESINS HEALTHCARE	FR
ANDROGEL 16,2 mg/g, gel	NL/H/3240/001	34009 300 537 1 3	BESINS HEALTHCARE	FR
ANDROGEL 16,2 mg/g, gel	NL/H/3240/001	34009 550 190 1 5	BESINS HEALTHCARE	FR
ANDROGEL 16,2 mg/g, gel	NL/H/3240/001	34009 550 190 2 2	BESINS HEALTHCARE	FR
Androgel 16.2 mg/g Gel	NL/H/3240/001	137119	BESINS HEALTHCARE	AT

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 16.2 mg/g, gel	NL/H/3240/001	201610276	BESINS HEALTHCARE	LU
ANDROGEL 25 mg Gel im Beutel	NL/H/3240/003	1-24744	LABORATOIRES BESINS INTERNATIONAL	AT
ANDROGEL 25 mg gél tasakban	NL/H/3240/003	OGYI-T-20015/01	LABORATOIRES BESINS INTERNATIONAL	HU
ANDROGEL 25 mg gels paciņa	NL/H/3240/003	05-0629	LABORATOIRES BESINS INTERNATIONAL	LV
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4151288	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4151387	LABORATOIRES BESINS INTERNATIONAL	PT

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 25 mg, gel em saqueta	NL/H/3240/003	4151486	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4151585	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4151684	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4151783	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4151882	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4151981	LABORATOIRES BESINS INTERNATIONAL	PT

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 25 mg, gel em saqueta	NL/H/3240/003	4152088	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4152187	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel em saqueta	NL/H/3240/003	4152286	LABORATOIRES BESINS INTERNATIONAL	PT
ANDROGEL 25 mg, gel en sachet-dose	NL/H/3240/003	BE248421	BESINS HEALTHCARE	BE
ANDROGEL 25 mg, gel en sachet-dose	NL/H/3240/003	357 634-4	LABORATOIRES BESINS INTERNATIONAL	FR
ANDROGEL 25 mg, gel en sachet-dose	NL/H/3240/003	357 536-2	LABORATOIRES BESINS INTERNATIONAL	FR

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 25 mg, gel en sachet-dose	NL/H/3240/003	563 547-6	LABORATOIRES BESINS INTERNATIONAL	FR
ANDROGEL 25 mg, gel en sachet-dose	NL/H/3240/003	563 143-2	LABORATOIRES BESINS INTERNATIONAL	FR
ANDROGEL 25 mg, gel en sachet-dose	NL/H/3240/003	0630/02/07/0049	LABORATOIRES BESINS INTERNATIONAL	LU
ANDROGEL 25 mg, gel in sachet	NL/H/3240/003	PA 1054/001/001	LABORATOIRES BESINS INTERNATIONAL	IE
ANDROGEL 25 mg, gel in sachet	NL/H/3240/003	RVG 27740	LABORATOIRES BESINS INTERNATIONAL	NL
Androgel 25 mg, gel v sacku	NL/H/3240/003	56/604/05-C	LABORATOIRES BESINS INTERNATIONAL	CZ

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, gel i brev	NL/H/3240/003	33561	LABORATOIRES BESINS INTERNATIONAL	DK
ANDROTOP	NL/H/3240/001	23380	BESINS HEALTHCARE	PL
ANDROTOP 20,25 mg/ pritisk gel	NL/H/3240/001	H/06/00194/023	BESINS HEALTHCARE	SI
ANDROTOP 20,25 mg/ pritisk gel	NL/H/3240/001	H/06/00194/024	BESINS HEALTHCARE	SI
ANDROTOP 20,25 mg/ pritisk gel	NL/H/3240/001	H/06/00194/025	BESINS HEALTHCARE	SI
ANDROTOP 20,25 mg/ pritisk gel	NL/H/3240/001	H/06/00194/026	BESINS HEALTHCARE	SI

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
ANDROTOP 25 mg gel v blazinici	NL/H/3240/003/MR	H/06/00194/001-011	LABORATOIRES BESINS INTERNATIONAL	SI
Androtop; 25 mg,zel w saszetce	NL/H/3240/003	12266	LABORATOIRES BESINS INTERNATIONAL	PL
ANDROTOP® GEL 25 mg Gel im Beutel Testosteron	NL/H/3240/003	54560.00.00	DR. KADE / BESINS PHARMA GMBH	DE
ANDROTOPIC 16,2 mg/g geeli	NL/H/3240/001	32444	BESINS HEALTHCARE	FI
Testarzon 20 mg/g gel transdermique	NL/H/3958/001	BE526613	FERRING N.V.	BE
Testarzon 20 mg/g gel transdermique	NL/H/3958/001	2018060215	FERRING N.V.	LU

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
Testarzon 20 mg/g Transdermal gel	NL/H/3958/001	PA 1009/028/001	FERRING IRELAND LTD.	IE
Testarzon 20 mg/g transdermālais gels	NL/H/3958/001	18-0062	FERRING GMBH	LV
Testarzon 20 mg/g transdermale gel	NL/H/3958/001	BE526613	FERRING N.V.	BE
Testarzon 20 mg/g transdermales Gel	NL/H/3958/001	BE526613	FERRING N.V.	BE
Testarzon 20 mg/g transdermales Gel	NL/H/3958/001	2018060215	FERRING N.V.	LU
Testarzon 20 mg/g transdermalni gel	NL/H/3958/001	HR-H-470331420	FERRING CONTROLLED THERAPEUTICS LIMITED	HR

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
Testarzon 20 mg/g transzdermális gél	NL/H/3958/001	OGYI-T-23359/01	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT.	HU
Testarzon 20 mg/g Διαδερμική γέλη	NL/H/3958/001	022832	FERRING HELLAS MEPE	CY
Testarzon 23 mg/pritisk transdermalni gel	NL/H/3958/001	H/18/02499/001	FERRING CONTROLLED THERAPEUTICS LIMITED	SI
Testavan 20 mg/g gel transdermic	NL/H/3958/001	10863/2018/01	FERRING CONTROLLED THERAPEUTICS LIMITED	RO
TESTAVAN 20 mg/g gel transdermico	NL/H/3958/001	045567017	FERRING S.P.A.	IT
Testavan 20 mg/g gel transdémico	NL/H/3958/001	83339	FERRING S.A.U.	ES

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
Testavan 20 mg/g gel transdérmico.	NL/H/3958/001	5744719	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.	PT
Testavan 20 mg/g gel voor transdermaal gebruik	NL/H/3958/001	RVG 120624	FERRING PHARMACEUTICALS LTD.	NL
Testavan 20 mg/g hlaup til notkunar um húð.	NL/H/3958/001	IS/1/18/040/01	FERRING LÆGEMIDLER A/S	IS
Testavan 20 mg/g transdermaaligeeli	NL/H/3958/001	34955	FERRING LÄÄKKEET OY	FI
Testavan 20 mg/g transdermaalne geel	NL/H/3958/001	963718	FERRING GMBH	EE

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
Testavan 20 mg/g Transdermal gel	NL/H/3958/001	PL 03194/0127	FERRING PHARMACEUTICALS LTD.	UK
Testavan 20 mg/g transdermal gel	NL/H/3958/001	55989	FERRING LÄKEMEDEL AB	SE
Testavan 20 mg/g transdermal gel	NL/H/3958/001	34955	FERRING LÄÄKKEET OY	FI
Testavan 20 mg/g Transdermal gel	NL/H/3958/001	MA832/01401	FERRING PHARMACEUTICALS LTD.	MT
Testavan 20 mg/g transdermalgel	NL/H/3958/001	17-11553	FERRING LEGEMIDLER AS	NO
Testavan 20 mg/g transdermální gel	NL/H/3958/001	56/025/17-C	FERRING PHARMACEUTICALS CZ S.R.O.	CZ

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
Testavan 20 mg/g transdermálny gél	NL/H/3958/001	56/0190/18-S	FERRING PHARMACEUTICALS CZ S.R.O.	SK
Testavan 20 mg/g transderminis gelis	NL/H/3958/001	LT/1/18/4217/001	FERRING GMBH	LT
TESTAVAN 20 mg/g, gel transdermique	NL/H/3958/001	34009 301 468 0 4	FERRING S.A.S.	FR
Testavan, 20 mg/g, żel przezskórny	NL/H/3958/001	24670	FERRING GMBH	PL
Testavan, transdermal gel	NL/H/3958/001	59066	FERRING LÆGEMIDLER A/S	DK
TESTAVAN® 20 mg/g transdermales Gel	NL/H/3958/001	99264.00.00	FERRING ARZNEIMITTEL GMBH	DE

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
Testavan® 20 mg/g Transdermales Gel	NL/H/3958/001	138290	FERRING ARZNEIMITTEL GES.M.B.H.	AT
Testim 50 mg Gel	UK/H/645/001	5149786	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.	PT
Testim 50 mg Gel	UK/H/645/001	5149885	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.	PT
Testim 50 mg Gel	UK/H/645/001	5149984	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.	PT

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 50 mg gel	IE/H/0834/001	RVG 30653	ENDO VENTURES LIMITED	NL
Testim 50 mg gel transdermico	UK/H/0645/001	036774014	FERRING S.P.A.	IT
Testim 50 mg gel transdermico	UK/H/0645/001	036774026	FERRING S.P.A.	IT
Testim 50 mg gel transdermico	UK/H/0645/001	036774038	FERRING S.P.A.	IT
Testim 50 mg gel transdermico	UK/H/0645/001	036774040	FERRING S.P.A.	IT
Testim 50 mg gel transdémico	UK/H/0645/001	66.461	FERRING S.A.U.	ES

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 50 mg Transdermaaligeeli	IE/H/0834/001	19237	ENDO VENTURES LIMITED	FI
TESTIM 50 mg Transdermal Gel	UK/H/0645/001	MA832/00901	FERRING PHARMACEUTICALS LTD.	MT
TESTIM 50 mg Transdermal Gel	UK/H/0645/001	PL 43808/0018	ENDO VENTURES LIMITED	UK
TESTIM 50 mg Transdermal Gel	UK/H/0645/001/MR	PA 2311/001/001	ENDO VENTURES LIMITED	IE
Testim 50 mg transdermalgel	IE/H/0834/001	04-2531	ENDO VENTURES LIMITED	NO
Testim 50 mg, transdermal gel	UK/H/0645/001	20719	FERRING LÄKEMEDEL AB	SE

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, transdermal gel	UK/H/0645/001/MR	36437	ENDO VENTURES LIMITED	DK
Testogel 16,2 mg/g gel	NL/H/3240/001	80.617	BESINS HEALTHCARE	ES
TESTOGEL 16.2 mg/g gel	NL/H/3240/001	PL 28397/0007	BESINS HEALTHCARE	UK
TESTOGEL 16.2 mg/g gel	NL/H/3240/001	PA1054/002/004	LABORATOIRES BESINS INTERNATIONAL	IE
Testogel Dosiergel 16,2 mg/g Gel	NL/H/3240/001	93105.00.00	DR. KADE / BESINS PHARMA GMBH	DE
Testotop Gel 125 mg	not available	63541.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE

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
Testotop Gel 62,5 mg	not available	63540.00.00	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTEL	DE
ТЕСТАБАН 20 mg/g трансдермален гел	NL/H/3958/001	20180149	FERRING CONTROLLED THERAPEUTICS LIMITED	BG