



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 (all formulations apart from topical use)

Procedure no.: PSUSA/00010631/201812



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
Andriol 40 mg capsule molli	not available	024585010	MSD ITALIA S.R.L.	IT
Andriol 40 mg capsule molli	not available	024585034	MSD ITALIA S.R.L.	IT
Andriol 40 mg kapsel, myk	not available	6598	MERCK SHARP & DOHME BV	NO
Andriol Testocaps 40 mg - Kapseln	not available	1-19756	NV ORGANON	AT
Andriol Testocaps 40 mg Kapseln Testosteronundecanoat	not available	59.01.00	MSD SHARP & DOHME GMBH	DE
Andriol Testocaps 40 mg lágy kapszula	not available	OGYI-T-9405/03	MSD PHARMA HUNGARY KFT.	HU

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
Andriol Testocaps, 40 mg capsules	not available	RVG 07531	NV ORGANON	NL
Andriol, bløde kapsler	not available	9264	MERCK SHARP & DOHME BV	DK
Andriol-T 40 mg cápsula mole	not available	4781183	MERCK SHARP & DOHME, LDA.	PT
Andriol-T 40 mg cápsula mole	not available	4781282	MERCK SHARP & DOHME, LDA.	PT
Andriol-T 40 mg cápsula mole	not available	4147989	MERCK SHARP & DOHME, LDA.	PT
ANDROTARDYL 250 mg/1 ml, solution injectable intramusculaire	not available	34 009 300 461 3 5	BAYER HEALTHCARE	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
Nebid 1000 mg/4ml, soluzione iniettabile	FI/H/0313/001	037051012	BAYER SPA	IT
Nebid 1000 mg/4ml, soluzione iniettabile	FI/H/0313/001	037051024	BAYER SPA	IT
Nebido 1000 mg /4 ml stungulyf, lausn	FI/H/0313/001	IS/1/04/026/01	BAYER AB	IS
Nebido 1000 mg/ 4 ml, injekční roztok	FI/H/0313/001	56/176/05-C	BAYER AG	CZ
Nebido 1000 mg/4 ml injekcinis tirpalas	FI/H/0313/001	LT/1/05/0222/001	BAYER AG	LT
Nebido 1000 mg/4 ml injekcinis tirpalas	FI/H/0313/001	LT/1/05/0222/002	BAYER AG	LT

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
Nebido 1000 mg/4 ml injekčný roztok	FI/H/0313/001	56/0144/05-S	BAYER AG	SK
Nebido 1000 mg/4 ml injeksjonsvæske, oppløsning	FI/H/0313/001	04- 2635	BAYER AB	NO
Nebido 1000 mg/4 ml injektioneste, liuos	FI/H/0313/001	17857	BAYER OY	FI
Nebido 1000 mg/4 ml Injektionslösung	FI/H/0313/001	2007060006	BAYER SA NV	LU
Nebido 1000 mg/4 ml Injektionslösung	FI/H/0313/001	1-25516	BAYER AUSTRIA GMBH	AT
Nebido 1000 mg/4 ml injektionsvätska, lösning	FI/H/0313/001	20890	BAYER 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
Nebido 1000 mg/4 ml otopina za injekciju	FI/H/0313/001	HR-H-728666888-01	BAYER DOO	HR
Nebido 1000 mg/4 ml otopina za injekciju	FI/H/0313/001	HR-H-728666888-02	BAYER DOO	HR
Nebido 1000 mg/4 ml raztopina za injiciranje	FI/H/0313/001	H/05/01097/001	BAYER D.O.O	SI
Nebido 1000 mg/4 ml raztopina za injiciranje	FI/H/0313/001	H/05/01097/002	BAYER D.O.O	SI
Nebido 1000 mg/4 ml šķīdums injekcijām	FI/H/0313/001	05-0141	BAYER AG	LV
Nebido 1000 mg/4 ml solução injetável	FI/H/0313/001	5159587	BAYER PORTUGAL 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
Nebido 1000 mg/4 ml solução injetável	FI/H/0313/001	5490057	BAYER PORTUGAL LDA	PT
Nebido 1000 mg/4 ml soluție injectabilă	not available	7615/2015/02	BAYER AG	RO
Nebido 1000 mg/4 ml soluție injectabilă	not available	7615/2015/01	BAYER AG	RO
Nebido 1000 mg/4 ml solution injectable	FI/H/0313/001	BE437132	BAYER SA NV	BE
Nebido 1000 mg/4 ml solution injectable	FI/H/0313/001	BE266384	BAYER SA NV	BE
Nebido 1000 mg/4 ml, oplossing voor injectie	FI/H/0313/001	RVG 30794	BAYER BV	NL

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
Nebido 1000 mg/4 ml, solution for injection	FI/H/0313/001	MA185/02701	BAYER PLC	MT
Nebido 1000 mg/4 ml, solution for injection	FI/H/0313/001	PL 00010/0549	BAYER PLC	UK
NEBIDO 1000 mg/4 ml, solution injectable	FI/H/0313/001	34009 367 582 7 8	BAYER HEALTHCARE	FR
NEBIDO 1000 mg/4 ml, solution injectable	FI/H/0313/001	34009 277 134 5 3	BAYER HEALTHCARE	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
Nebido 1000 mg/4ml injektionsvæske, opløsning	FI/H/0313/001	36481	BAYER AB	DK
Nebido 1000 mg/4ml solution for injection	FI/H/0313/001	PA 1410/20/1	BAYER LTD	IE
Nebido 1000 mg/4ml ενέσιμο διάλυμα	FI/H/0313/001	19681/31-5-2005	BAYER HELLAS SA	CY

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
Nebido 1000 mg/4ml ενέσιμο διάλυμα	FI/H/0313/001	43456/04/12-1-2005	BAYER HELLAS SA	GR
Nebido 250 mg/ml oldatos injekció	FI/H/0313/001	OGYI-T-10175/01	BAYER AG	HU
Nebido 250 mg/ml oldatos injekció	FI/H/0313/001	OGYI-T-10175/02	BAYER AG	HU
Nebido, 1000 mg/4 ml, roztwór do wstrzykiwań	FI/H/0313/001	11740	BAYER AG	PL
Nebido, 1000 mg/4 ml, süstelahus	FI/H/0313/001	472505	BAYER AG	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
Nebido® 1000 mg Injektionslösung	FI/H/0313/001	60074.00.00	JENAPHARM GMBH & CO KG	DE
Panteston 40 mg kapselit	not available	7845	MERCK SHARP & DOHME BV	FI
Panteston 40 mg kapslar	not available	7845	MERCK SHARP & DOHME BV	FI
PANTESTONE 40 mg, capsule molle	not available	34009 377 647 4 2	MSD FRANCE	FR
PANTESTONE 40 mg, capsule molle	not available	34009 377 648 0 3	MSD FRANCE	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
PANTESTONE 40 mg, capsule molle	not available	34009 379 817 4 3	MSD FRANCE	FR
Reandron 1000 mg/4 ml, solución inyectable	FI/H/0313/001	66.470	BAYER HISPANIA SL	ES
Restandol Testocaps 40 mg soft capsules	not available	PA 1286/54/1	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
RESTANDOL TESTOCAPS 40 mg καψάκια	not available	41177/10/31-5-2011	MSD GREECE	GR

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
Restandol® TestocapsTM 40 mg capsule	not available	PL 00025/0595	MERCK SHARP & DOHME LTD.	UK
SUSTANON '250', solution injectable	not available	BE 012704	ASPEN PHARMA TRADING LIMITED	BE
SUSTANON '250', solution injectable	not available	2007129574	ASPEN PHARMA TRADING LIMITED	LU
Sustanon "250" injektioneste, liuos	not available	3811	ASPEN PHARMA TRADING LIMITED	FI
Sustanon "250" injektionsvätska, lösning	not available	3811	ASPEN PHARMA TRADING LIMITED	FI

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
Sustanon 250 250 mg/ml injekčný roztok	not available	56/0357/91-C/S	ASPEN PHARMA TRADING LIMITED	SK
SUSTANON 250 250 mg/ml, injekční roztok	not available	56/357/91-C	ASPEN PHARMA TRADING LIMITED	CZ
Sustanon 250 mg/ml injekcinis tirpalas	not available	LT/1/97/1261/003	ASPEN PHARMA TRADING LIMITED	LT
Sustanon 250 mg/ml šķīdums injekcijām	not available	97-0497	ASPEN PHARMA TRADING LIMITED	LV
Sustanon 250 mg/ml soluzione iniettabile per uso intramuscolare	not available	016094017	ASPEN PHARMA TRADING LIMITED	IT
Sustanon 250 mg/ml süstelahus	not available	211498	ASPEN PHARMA TRADING LIMITED	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
Sustanon 250 mg/ml, oplossing voor injectie	not available	RVG 00027	ASPEN PHARMA TRADING LIMITED	NL
Sustanon 250, 250 mg/ml solution for injection	not available	PL 39699/0059	ASPEN PHARMA TRADING LIMITED	UK
Sustanon 250, Injektionslösung	not available	BE 012704	ASPEN PHARMA TRADING LIMITED	BE
Sustanon 250, Injektionslösung	not available	2007129574	ASPEN PHARMA TRADING LIMITED	LU
SUSTANON '250', oplossing voor injectie	not available	BE 012704	ASPEN PHARMA TRADING LIMITED	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
Sustenon 250 mg/1 ml solução injetável	not available	8890012	ASPEN PHARMA TRADING LIMITED	PT
Testex 25 mg/1 ml solución inyectable	not available	19.207	DESMA LABORATORIO FARMACÉUTICO SL	ES
Testex Prolongatum 100 mg/2 ml solución inyectable	not available	61.865	DESMA LABORATORIO FARMACÉUTICO SL	ES
Testex Prolongatum 250 mg/2 ml solución inyectable	not available	27.691	DESMA LABORATORIO FARMACÉUTICO SL	ES
TESTOCAPS® 40 mg capsules molles	not available	BE 113793	MSD BELGIUM BVBA/SPRL	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
TESTOCAPS® 40 mg capsules molles	not available	2007079379	MSD BELGIUM BVBA/SPRL	LU
TESTOCAPS® 40 mg capsules, zacht	not available	BE 113793	MSD BELGIUM BVBA/SPRL	BE
TESTOCAPS® 40 mg Weichkapseln	not available	BE 113793	MSD BELGIUM BVBA/SPRL	BE
Testosteron-Depot GALEN® 250 mg Injektionslösung	not available	6139519.00.00	GALENPHARMA GMBH	DE
Testosteron-Depot Jenapharm 250 mg/1 ml Injektionslösung	not available	3000306.00.00	JENAPHARM GMBH & CO KG	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
Testosteron-Depot JENAPHARM 250 mg/1 ml Injektionslösung	not available	3000307.00.00	JENAPHARM GMBH & CO KG	DE
Testosterone Enantate 250 mg/ ml Solution for Injection	not available	PL 16853/0116	ALLIANCE PHARMACEUTICALS LTD	UK
Testoviron 250 mg/ml soluzione iniettabile a rilascio prolungato per uso intramuscolare	not available	002922060	BAYER SPA	IT
Testoviron Depot 250 mg/ml solução injetável	not available	8888222	BAYER PORTUGAL LDA	PT
Testoviron®-Depot-250 250 mg/1 ml Injektionslösung	not available	6929279.00.00	JENAPHARM GMBH & CO KG	DE
TESTOVIS 100 mg/2 ml soluzione iniettabile per uso intramuscolare	not available	003559059	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT

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
Undestor Testocaps 40 mg capsule moi	not available	1076/2008/01	MERCK SHARP & DOHME ROMANIA SRL	RO
Undestor Testocaps 40 mg capsule moi	not available	1076/2008/02	MERCK SHARP & DOHME ROMANIA SRL	RO
Undestor Testocaps 40 mg capsule moi	not available	1076/2008/03	MERCK SHARP & DOHME ROMANIA SRL	RO
Undestor Testocaps 40 mg mäkke kapsuly	not available	56/0091/03-S	MERCK SHARP & DOHME BV	SK

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
Undestor Testocaps, 40 mg mjuk kapsel	not available	9559	MERCK SHARP & DOHME BV	SE
Undestor Testocaps, 40 mg, kapsułki	not available	R/2344	MSD POLSKA SP. Z O.O.	PL
Undestor® 40 mg, měkké tobolky	not available	56/023/91-S/C	MERCK SHARP & DOHME BV	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
Virormone (100 mg/2 ml)	not available	PL00111/0203	DHP HEALTHCARE LTD	UK
НЕБИДО 250 mg/ml инжекционен разтвор	not available	20060085	BAYER AG	BG