



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 September 2022  
EMA/725899/2022  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: testosterone (all formulations apart from topical use)

Procedure no.: PSUSA/00010631/202112

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Testoviron 250 mg/ml soluzione iniettabile a rilascio prolungato per uso intramuscolare	not available	002922060	BAYER SPA	IT
Testovis 100 mg/2 ml soluzione iniettabile per uso intramuscolare	not available	003559059	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Sustanon 250 250 mg/ml injekčný roztok	not available	56/0357/91-C/S	ASPEN PHARMA TRADING LIMITED	SK
Sustanon 250 mg/ml šķīdums injekcijām	not available	97-0497	ASPEN PHARMA TRADING LIMITED	LV
Testosterone Enantate 250 mg/ ml Solution for Injection.	not available	PL 16853/0116	ALLIANCE PHARMACEUTICALS LTD	XI
Sustenon 250 mg /1 ml solução injectável	not available	8890012	ASPEN PHARMA TRADING LIMITED	PT
Sustanon "250" injektioneste, liuos	not available	3811	ASPEN PHARMA TRADING LIMITED	FI
Sustanon "250" injektionsvätska, lösning	not available	3811	ASPEN PHARMA TRADING LIMITED	FI
Sustanon 250 mg/ml soluzione iniettabile per uso intramuscolare	not available	016094017	ASPEN PHARMA TRADING LIMITED	IT

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Testosteron-Depot GALEN® 250 mg Injektionslösung	not available	6139519.00.00	GALENPHARMA GMBH	DE
Testosteron-Depot GALEN® 250 mg Injektionslösung	not available	6139519.00.00	GALENPHARMA GMBH	DE
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
Sustanon 250 mg/ml, injekční roztok	not available	56/357/91-C	ASPEN PHARMA TRADING LIMITED	CZ
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
PANTESTONE 40 mg, capsule molle	not available	34009 379 817 4 3	MSD FRANCE	FR

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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
Testosterone Enantate 250 mg/ ml Solution for Injection.	not available	PL 16853/0116	ALLIANCE PHARMACEUTICALS LTD	XI
Testoviron®-Depot-250 250 mg/1 ml Injektionslösung	not available	6929279.00.00	JENAPHARM GMBH & CO KG	DE
Sustanon 250 mg/ml, oplossing voor injectie	not available	RVG 00027	ASPEN PHARMA TRADING LIMITED	NL
Nebido 1000 mg/4 ml injektionsvätska, lösning	FI/H/0313/001	17857	BAYER OY	FI
Nebido 1000 mg/4 ml solution injectable	FI/H/0313/001	BE437132	BAYER SA NV	BE
Nebido 1000 mg/4 ml Injektionslösung	FI/H/0313/001	BE266384	BAYER SA NV	BE

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Nebido 1000 mg/4 ml Injektionslösung	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, 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
Nebido 1000 mg/4 ml Injektionslösung	FI/H/0313/001	2007060006	BAYER SA NV	LU
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/4ml ενέσιμο διάλυμα	FI/H/0313/001	19681/31-5-2005	BAYER HELLAS SA	CY
Nebido 1000 mg/4 ml Injektionslösung	FI/H/0313/001	1-25516	BAYER AUSTRIA GMBH	AT

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Nebido 1000 mg/4 ml oplossing voor injectie	FI/H/0313/001	BE266384	BAYER SA NV	BE
Nebido 1000 mg/4 ml injektioneste, liuos	FI/H/0313/001	17857	BAYER OY	FI
Nebido 1000 mg/ 4 ml injekční roztok	FI/H/0313/001	56/176/05-C	BAYER AG	CZ
Nebido 1000 mg/4 ml solution injectable	FI/H/0313/001	2007060006	BAYER SA NV	LU
Nebido 1000 mg/4ml injektionsvæske, opløsning	FI/H/0313/001	36481	BAYER AB	DK
Nebido 1000 mg/4 ml solução injetável	FI/H/0313/001	5159587	BAYER PORTUGAL LDA	PT
Nebido 1000 mg/4 ml injeksjonsvæske, oppløsning	FI/H/0313/001	04- 2635	BAYER AB	NO
Nebido, 1000 mg/4 ml, roztwór do wstrzykiwań	FI/H/0313/001	11740	BAYER AG	PL
Nebido 1000 mg/4ml ενέσιμο διάλυμα	FI/H/0313/001	43456/04/12-1-2005	BAYER HELLAS SA	GR

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Nebido 1000 mg /4 ml stungulyf, lausn.	FI/H/0313/001	IS/1/04/026/01	BAYER AB	IS
Nebido® 1000 mg Injektionslösung	FI/H/0313/001	60074.00.00	JENAPHARM GMBH & CO KG	DE
Nebido 250 mg/ml oldatos injekció	FI/H/0313/001	OGYI-T-10175/01	BAYER AG	HU
Nebido 1000 mg/4 ml injekcinis tirpalas	FI/H/0313/001	LT/1/05/0222/001	BAYER AG	LT
Nebido, 1000 mg/4 ml, süstelahus	FI/H/0313/001	472505	BAYER AG	EE
Nebido 1000 mg/4 ml, oplossing voor injectie	FI/H/0313/001	RVG 30794	BAYER BV	NL
Nebido 1000 mg/4 ml injektionsvätska, lösning	FI/H/0313/001	20890	BAYER AB	SE
Nebido 1000 mg/4 ml šķīdums injekcijām	FI/H/0313/001	05-0141	BAYER AG	LV
Nebido 1000 mg/4 ml injekčný roztok	FI/H/0313/001	56/0144/05-S	BAYER AG	SK

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Nebido 1000 mg/4ml, soluzione iniettabile.	FI/H/0313/001	037051012	BAYER SPA	IT
Nebido 1000 mg/4ml solution for injection	FI/H/0313/001	MA639/02301	BAYER LTD	MT
Nebido 1000 mg/4 ml solução injetável	FI/H/0313/001	5490057	BAYER PORTUGAL LDA	PT
Nebido 1000 mg/4 ml injekcinis tirpalas	FI/H/0313/001	LT/1/05/0222/002	BAYER AG	LT
Nebido 1000 mg/4 ml oplossing voor injectie	FI/H/0313/001	BE437132	BAYER SA NV	BE
Nebido 250 mg/ml oldatos injekció	FI/H/0313/001	OGYI-T-10175/02	BAYER AG	HU
НЕБИДО 250 mg/ml инжекционен разтвор	FI/H/0313/001	20060085	BAYER AG	BG
Nebido 1000 mg/4 ml otopina za injekciju	FI/H/0313/001	HR-H-728666888	BAYER DOO	HR
Nebido 1000 mg/4ml solution for injection	FI/H/0313/001	PA1410/020/001	BAYER LTD	IE



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Nebido 1000 mg/4 ml soluție injectabilă	FI/H/0313/001	14072/2021/01	BAYER AG	RO
Nebido 1000 mg/4 ml soluție injectabilă	FI/H/0313/001	14072/2021/02	BAYER AG	RO
Nebid 1000 mg/4ml, soluzione iniettabile.	FI/H/0313/001	037051024	BAYER SPA	IT
Andriol Testocaps 40 mg lágy kapszula	not available	OGYI-T-9405/03	MSD PHARMA HUNGARY KFT.	HU
Andriol Testocaps 40 mg lágy kapszula	not available	OGYI-T-9405/01	MSD PHARMA HUNGARY KFT.	HU
Andriol Testocaps 40 mg lágy kapszula	not available	OGYI-T-9405/02	MSD PHARMA HUNGARY KFT.	HU
SUSTANON 250, solution injectable	not available	BE 012704	ASPEN PHARMA TRADING LIMITED	BE
SUSTANON 250, oplossing voor injectie	not available	BE 012704	ASPEN PHARMA TRADING LIMITED	BE
Sustanon 250, Injektionslösung	not available	BE 012704	ASPEN PHARMA TRADING LIMITED	BE

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Andriol Testocaps 40 mg Kapseln Testosteronundecanoat	not available	59.01.00	MSD SHARP & DOHME GMBH	DE
Testoviron Depot 250 mg/ml solução injetável.	not available	8888222	BAYER PORTUGAL LDA	PT
Sustanon 250, 250mg/ml solution for injection	not available	PL 39699/0059	ASPEN PHARMA TRADING LIMITED	XI
ANDROTARDYL 250 mg/1 ml, solution injectable intramusculaire	not available	34 009 300 461 3 5	BAYER HEALTHCARE	FR
Testosteron-Depot Jenapharm 250 mg/1 ml Injektionslösung	not available	3000306.00.00	JENAPHARM GMBH & CO KG	DE
Undestor Testocaps, 40 mg, kapsuľki	not available	R/2344	MSD POLSKA SP. Z O.O.	PL
Sustanon 250 mg/ml injekcinis tirpalas	not available	LT/1/97/1261/003	ASPEN PHARMA TRADING LIMITED	LT
Undestor Testocaps 40 mg mäkké kapsuly	not available	56/0091/03-S	MERCK SHARP & DOHME BV	SK
Sustanon 250 mg/ml süstelahus	not available	211498	ASPEN PHARMA TRADING LIMITED	EE

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SUSTANON 250, solution injectable	not available	2007129574	ASPEN PHARMA TRADING LIMITED	LU
Sustanon 250, Injektionslösung	not available	2007129574	ASPEN PHARMA TRADING LIMITED	LU
Panteston 40 mg kapslar	not available	7845	MERCK SHARP & DOHME BV	FI
Panteston 40 mg kapselit	not available	7845	MERCK SHARP & DOHME BV	FI
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