



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2017
EMA/590501/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): testosterone undecanoate (injection)

Procedure No.: PSUSA/00010161/201612



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, soluzione iniettabile.	FI/H/0313/001	037051012	BAYER SPA	IT
Nebido 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 PHARMA AG	IS
Nebido 1000 mg/ 4 ml, injekční roztok	FI/H/313/01	56/176/05-C	BAYER PHARMA AG	CZ
Nebido 1000 mg/4 ml injekcinis tirpalas	FI/H/0313/001	LT/1/05/0222/001	BAYER PHARMA AG	LT
Nebido 1000 mg/4 ml injekcinis tirpalas	FI/H/0313/001	LT/1/05/0222/002	BAYER PHARMA AG	LT
Nebido 1000 mg/4 ml injekčný roztok	FI/H/0313/001	56/0144/05-S	BAYER PHARMA AG	SK
Nebido 1000 mg/4 ml injeksjonsvæske, oppløsning	FI/H/0313/001	04- 2635	BAYER PHARMA AG	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	1-25516	BAYER AUSTRIA GMBH	AT
Nebido 1000 mg/4 ml Injektionslösung	FI/H/313/01	BE266384	BAYER SA NV	BE
Nebido 1000 mg/4 ml Injektionslösung	FI/H/0313/001	BE437132	BAYER SA NV	BE
Nebido 1000 mg/4 ml Injektionslösung	FI/H/313/01	2007060006	BAYER SA NV	LU
Nebido 1000 mg/4 ml injektionsvätska, lösning	FI/H/0313/001	17857	BAYER OY	FI
Nebido 1000 mg/4 ml injektionsvätska, lösning	FI/H/0313/001	20890	BAYER PHARMA AG	SE
Nebido 1000 mg/4 ml oplossing voor injectie	FI/H/313/01	BE266384	BAYER SA NV	BE
Nebido 1000 mg/4 ml oplossing voor injectie	FI/H/0313/001	BE437132	BAYER SA NV	BE
Nebido 1000 mg/4 ml otopina za injekciju	FI/H/0313/001	HR-H-728666888-01	BAYER DOO	HR

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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/313/01	H/05/01097/001	BAYER PHARMA AG	SI
Nebido 1000 mg/4 ml raztopina za injiciranje	FI/H/313/01	H/05/01097/002	BAYER PHARMA AG	SI
Nebido 1000 mg/4 ml solução injetável	FI/H/0313/001	5159587	BAYER PORTUGAL LDA	PT
Nebido 1000 mg/4 ml solução injetável	FI/H/0313/001	5490057	BAYER PORTUGAL LDA	PT
Nebido 1000 mg/4 ml solutie injectabilă	not available	7615/2015/01-02	BAYER PHARMA 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/313/01	BE266384	BAYER SA NV	BE
Nebido 1000 mg/4 ml solution injectable	FI/H/0313/001	2007060006	BAYER SA NV	LU
Nebido 1000 mg/4 ml, oplossing voor injectie	FI/H/0313/001	RVG 30794	BAYER BV	NL
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/313/01	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
Nebido 1000 mg/4ml injektionsvæske, opløsning	FI/H/313/01	36481	BAYER PHARMA AG	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

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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 PHARMA AG	HU
Nebido 250 mg/ml oldatos injekció	FI/H/0313/001	OGYI-T-10175/02	BAYER PHARMA AG	HU
Nebido, 1000 mg/4 ml, roztwór do wstrzykiwań	FI/H/0313/001	11740	BAYER PHARMA AG	PL
Nebido, 1000 mg/4 ml, süstelahus	FI/H/313/01	472505	BAYER PHARMA AG	EE
Nebido® 1000 mg Injektionslösung Testosteronundecanoat	FI/H/0313/001	60074.00.00	JENAPHARM GMBH & CO KG	DE
Reandron 1000 mg/4 ml, solución inyectable.	FI/H/313/01	66.470	BAYER HISPANIA SL	ES
НЕБИДО 250 mg/ml, инжекционен разтвор	not available	20060085	BAYER PHARMA AG	BG