12 April 2018
EMA/365906/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): leuprorelin

Procedure No.: PSUSA/00001844/201707

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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
Procren Depot pulver og solvens til injektionsvæske, suspension, fyldt injektionssprøjte 3,75 mg	not available	36846	ABBVIE A/S	DK
GINECRIN DEPOT 3,75 mg polvo y disolvente para suspensión inyectable	not available	59344	ABBVIE SPAIN S.L.U.	ES
Lutrate 3 month Depot 22.5 mg powder and solvent for prolonged-release suspension for injection	UK/H/6582/002	PL 12762/0510	MERCURY PHARMACEUTICALS LTD.	UK
Lutrate 1 month Depot 3.75 mg powder and solvent for prolonged-release suspension for injection	UK/H/6582/001	PL 12762/0509	MERCURY PHARMACEUTICALS LTD.	UK
Lutrate 3 month Depot powder and solvent for prolonged-release suspension for injection	UK/H/6582/002	PA0899/044/002	MERCURY PHARMACEUTICALS LTD.	IE
Lutrate 1 month Depot 3.75 mg Powder and Solvent for Prolonged-Release Suspension for Injection	UK/H/6582/001	PA0899/044/001	MERCURY PHARMACEUTICALS LTD.	IE
Enanton Depot Dual, 11,25 mg, pulver og væske til injeksjonsvæske, suspensjon, ferdigfylt sprøyte	not available	05-3193	ORION CORPORATION	NO
Enanton Depot Dual, 3,75 mg, pulver og væske til injeksjonsvæske, suspensjon, ferdigfylt sprøyte	not available	05-3192	ORION CORPORATION	NO
Enanton Depot Dual 30 mg pulver og væske til injeksjonsvæske, suspensjon, ferdigfylt sprøyte	not available	06-4184	ORION CORPORATION	NO
Enanton Depot Set 11,25 mg pulver og væske til injeksjonsvæske, suspensjon	not available	04-2706	ORION CORPORATION	NO
Enanton Depot Set 3,75 mg pulver og væske til injeksjonsvæske, suspensjon	not available	04-2705	ORION CORPORATION	NO
Enanton Depot Set 30 mg pulver og væske til injeksjonsvæske, suspensjon	not available	06-4353	ORION CORPORATION	NO
Leuprorelin Sandoz 3,6 mg implantat	DE/H/1681/001	09-6592	SANDOZ A/S	NO
Leuprorelin Sandoz 5 mg implantat	DE/H/1681/002	09-6593	SANDOZ A/S	NO
Lerin 5 mg implantat	/	UP/I-530-09/12-01/70	SANDOZ D.O.O.	HR
LEPTOPROL 5 mg IMPLANT	DE/H/3873/001	7133/2014/01	S.C. SANDOZ S.R.L.	RO
LEPTOPROL 5 mg IMPLANT	DE/H/3873/001	7133/2014/02	S.C. SANDOZ S.R.L.	RO

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
LEPTOPROL 5 mg IMPLANT	DE/H/3873/001	7133/2014/03	S.C. SANDOZ S.R.L.	RO
LEPTOPROL 5 mg IMPLANT	DE/H/3873/001	7133/2014/04	S.C. SANDOZ S.R.L.	RO
Leuprorelin Sandoz 5 mg implantaatti	DE/H/3873/001	31486	SANDOZ A/S	FI
LEPTOPROL 5 mg Fertigspritze mit Implantat	DE/H/3873/001	89944.00.00	HEXAL AG	DE
LEPTOPROL 5 mg Implantát v předplněné injekční stříkačce	DE/H/3873/001	44/076/15-C	SANDOZ S.R.O.	CZ
Leptoprol 5 mg implantat v napolnjeni injekcijski brizgi	DE/H/3873/001	H/14/01952/001	SANDOZ PHARMACEUTICALS D.D.	SI
Leptoprol 5 mg implantat v napolnjeni injekcijski brizgi	DE/H/3873/001	H/14/01952/002	SANDOZ PHARMACEUTICALS D.D.	SI
Leptoprol 5 mg implantat v napolnjeni injekcijski brizgi	DE/H/3873/001	H/14/01952/003	SANDOZ PHARMACEUTICALS D.D.	SI
Leptoprol 5 mg implantat v napolnjeni injekcijski brizgi	DE/H/3873/001	H/14/01952/004	SANDOZ PHARMACEUTICALS D.D.	SI
Leuprorelina Trimestral Sandoz 5 mg implante en jeringa precargada	DE/H/3873/001	79581	SANDOZ FARMACÉUTICA, S.A.	ES
Leuprorelin Sandoz 3,6 mg implantat	DE/H/1681/001	42228	SANDOZ A/S	SE
Leptoprol 5 mg implants pilnšļircē	DE/H/3873/001	14-0265	SANDOZ PHARMACEUTICALS D.D.	LV
Leuprorelin Sandoz 3,6 mg implantátum	DE/H/1681/001	OGYI-T-21283/01	SANDOZ HUNGÁRIA KFT	HU
Prostaplant 5 mg εμφύτευμα	DE/H/1681/002	71627/30-9-2016	SANDOZ GMBH	GR
LEPTOPROL 5 mg, implant en seringue pré-remplie	DE/H/3873/001	34009 300 200 0 5	SANDOZ	FR
Leuprorelin/Sandoz 5 mg, εμφύτευμα σε προγεμισμένη σύριγγα	DE/H/3873/001	67956/9-10-2015	SANDOZ PHARMACEUTICALS D.D.	GR
Leuproreline Sandoz depot 1 maand 3,6 mg, implantaat	not available	RVG 33195	SANDOZ B.V.	NL
Leuproreline Sandoz depot 3 maanden 5 mg, implantaat	not available	RVG 30594	SANDOZ B.V.	NL
Leuprorelin Sandoz 3,6 mg - Implantat für 1 Monat	DE/H/1681/001	1-28962	SANDOZ GMBH	AT
Leuprorelin "Sandoz"	DE/H/1681/001	44771	SANDOZ A/S	DK
Leuprorelin Sandoz 3,6 mg implantátum	DE/H/1681/001	OGYI-T-21283/01	SANDOZ HUNGÁRIA KFT	HU
Leuprorelin Sandoz 5 mg implantátum	DE/H/1681/002	OGYI-T-21283/02	SANDOZ HUNGÁRIA KFT	HU
Leuprorelin Sandoz 5 mg implantát	DE/H/1681/002	56/0564/09-S	SANDOZ PHARMACEUTICALS D.D.	SK
LEUPROSTIN, 3,6 MG, IMPLANT	DE/H/1681/001	17716	SANDOZ GMBH	PL

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
Leuprorelin Sandoz 5 mg - Implantat für 3 Monate	DE/H/1681/002	1-28963	SANDOZ GMBH	AT
LEUPROSTIN, 5 MG, IMPLANT	DE/H/1681/002	17717	SANDOZ GMBH	PL
Leupro-Sandoz 1-Monats-Depot	not available	62070.00.00	HEXAL AG	DE
Leuprone® HEXAL® 3-Monatsdepot	not available	61260.00.00	HEXAL AG	DE
Leupro-Sandoz 3-Monats-Depot	not available	61262.00.00	HEXAL AG	DE
Leuprone® HEXAL® 1-Monatsdepot	not available	62068.00.00	HEXAL AG	DE
Leuprorelin Sandoz 3,6 mg implantát	DE/H/1681/001	56/0563/09-S	SANDOZ PHARMACEUTICALS D.D.	SK
Leuprorelin "Sandoz"	DE/H/1681/002	44772	SANDOZ A/S	DK
Leuprorelin Sandoz 5 mg implantat	DE/H/1681/002	42229	SANDOZ A/S	SE
Leuprorelin HEXAL 5 mg	DE/H/1681/002	61261.00.00	HEXAL AG	DE
Leuprorelin HEXAL 3,6 mg	DE/H/1681/001	62069.00.00	HEXAL AG	DE
ELIGARD 45 mg prašak i otapalo za otopinu za injekciju	not available	UP/I-530-09/12-01/680	ASTELLAS D.O.O.	HR
ELIGARD 22,5 mg prašak i otapalo za otopinu za injekciju	not available	UP/I-530-09/13-02/133	ASTELLAS D.O.O.	HR
ELIGARD 7,5 mg prašak i otapalo za otopinu za injekciju	not available	UP/I-530-09/13-02/132	ASTELLAS D.O.O.	HR
Procren Depot 3,75 mg pulver og væske til injeksjonsvæske, suspensjon i tokammersprøyte	not available	04-2944	ABBVIE AS	NO
Procren Depot 11,25 mg pulver og væske til injeksjonsvæske, suspensjon i tokammersprøyte	not available	02-550	ABBVIE AS	NO
Procren Depot 30 mg pulver og væske til injeksjonsvæske, suspensjon i tokammersprøyte	not available	07-5124	ABBVIE AS	NO
Lucrin, oplossing voor injectie 5 mg/ml	not available	RVG 11645	ABBVIE B.V.	NL
Lucrin Depot, poeder en oplosmiddel voor suspensie voor injectie 3,75 mg	not available	RVG 14351	ABBVIE B.V.	NL
Lucrin Depot 11,25 mg, poeder en oplosmiddel voor suspensie voor injectie	not available	RVG 21165	ABBVIE B.V.	NL
Lucrin PDS Depot 1 maand 3,75 mg, poeder en oplosmiddel voor suspensie voor injectie	not available	RVG 30197	ABBVIE B.V.	NL
Lucrin PDS Depot 3 maanden 11,25 mg,	not available	RVG 30198	ABBVIE B.V.	NL

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poeder en oplosmiddel voor suspensie voor injectie				
Lucrin PDS Depot 6 maanden 30 mg, poeder en oplosmiddel voor suspensie voor injectie	not available	RVG 100696	ABBVIE B.V.	NL
Procren Depot PDS 3,75 mg injektiokuiva-aine ja liuotin, suspensiota varten, esitäytetty ruisku	not available	19030	ABBVIE OY	FI
Procren Depot PDS 11,25 mg injektiokuiva-aine ja liuotin, suspensiota varten, esitäytetty ruisku	not available	17246	ABBVIE OY	FI
Procren Depot PDS 30 mg injektiokuiva-aine ja liuotin, suspensiota varten, esitäytetty ruisku	not available	23837	ABBVIE OY	FI
Procren Depot PDS 3,75 mg pulver och vätska till injektionsvätska, suspension, förfylld spruta	not available	19030	ABBVIE OY	FI
Procren Depot PDS 11,25 mg pulver och vätska till injektionsvätska, suspension, förfylld spruta	not available	17246	ABBVIE OY	FI
Procren Depot PDS 30 mg pulver och vätska till injektionsvätska, suspension, förfylld spruta	not available	23837	ABBVIE OY	FI
Procrin Mensual 3,75 mg polvo y disolvente para suspensión inyectable en jeringa precargada	not available	74094	ABBVIE SPAIN S.L.U.	ES
DARONDA 14 mg/2,8 ml / VIAL, ενέσιμο διάλυμα	not available	20748/01-04-2008	ABBVIE PHARMACEUTICALS S.A.	GR
Lucrin PDS Depot 3,75 mg por és oldószer szuszpenziós injekcióhoz előretöltött fecskendőben	not available	OGYI-T-10040/01	ABBVIE KFT	HU
Lucrin PDS Depot 11,25 mg por és oldószer szuszpenziós injekcióhoz előretöltött fecskendőben	not available	OGYI-T-10040/02	ABBVIE KFT	HU
Procren Depot 3,75 mg, pulver och vätska till injektionsvätska, suspension i förfylld spruta	not available	20487	ABBVIE 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
Procren Depot 11,25 mg, pulver och vätska till injektionsvätska, suspension i förfylld spruta	not available	18114	ABBVIE AB	SE
Procren Depot 30 mg, pulver och vätska till injektionsvätska, suspension i förfylld spruta	not available	25836	ABBVIE AB	SE
Lutrate Depot, 3,75 mg, proszek i rozpuszczalnik do sporządzania zawiesiny do wstrzykiwań o przedłużonym uwalnianiu	ES/H/0141/001	21174	ANGELINI PHARMA ÖSTERREICH GMBH	PL
Politrate 3,75 mg Polvere e solvente per sospensione iniettabile a rilascio prolungato	ES/H/0141/001	041465016	GP-PHARM S.A.	IT
Lutrate Depot 3,75 mg pulveris un šķīdinātājs ilgstošas darbības injekciju suspensijas pagatavošanai	ES/H/0141/001	12-0199	ANGELINI PHARMA ÖSTERREICH GMBH	LV
Lutrate Depot 3,75 mg milteliai ir tirpiklis pailginto atpalaidavimo injekcinei suspensijai	ES/H/0141/001	LT/1/12/3051/001	ANGELINI PHARMA ÖSTERREICH GMBH	LT
Lutrate Depot 3,75 mg prášok a disperzné prostredie na injekcnú suspenziu s predlženým uvolnovaním	ES/H/0141/001	56/0430/12-S	ANGELINI PHARMA ÖSTERREICH GMBH	SK
Politrate Depot 22.5 mg powder and solvent for prolonged-release suspension for injection	ES/H/0141/002	PL 25859/0005	GP-PHARM S.A.	UK
Lutrate Depot 22,5 mg poudre et solvant pour suspension injectable à libération prolongée	ES/H/0141/002	BE474115	GP-PHARM S.A.	BE
Leuprorelin 3-month Depot 22.5mg Powder and Solvent for Prolonged-release Suspension for Injection	ES/H0141/002	PA1766/001/002	GP-PHARM S.A.	IE
Politrate 22,5 mg pulver och vätska till injektionsvätska, depotsuspension	ES/H/0141/002	51171	GP-PHARM S.A.	SE
Lutrate Depot 22,5 mg/2 ml pó e veículo para suspensão injetável de libertação prolongada	ES/H/0141/002	5652615	GP-PHARM S.A.	PT
Lutrate Depot 22,5 mg Pulver und	ES/H/0141/002	136252	ANGELINI PHARMA ÖSTERREICH	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
Lösungsmittel zur Herstellung einer Depot-Injektionssuspension			GMBH	
Lutrate Depot Trimestral 22,5 mg polvo y disolvente para suspensión de liberación prolongada inyectable	ES/H/0141/002	80000	GP-PHARM S.A.	ES
Lutrate Depot 22,5 mg, toimeainet prolongeeritult vabastava süstesuspensiooni pulber ja lahusti	ES/H/0141/002	878115	ANGELINI PHARMA ÖSTERREICH GMBH	EE
Lutrate Depot 22,5 mg prášek a rozpouštědlo pro injekční suspenzi s prodlouženým účinkem	ES/H/0141/002	44/301/15-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
Lutrate Depot 22,5 mg прах и разтворител за инжекционна суспензия с удължено освобождаване	ES/H/0141/002	20150211	ANGELINI PHARMA ÖSTERREICH GMBH	BG
Lutrat Depot 22.5 mg pulver og solvens til depotinjektionsvæske, suspension	ES/H/0141/002	54183	GP-PHARM S.A.	DK
Lutrate Depot 3,75 mg polvo y disolvente para suspensión de liberación prolongada inyectable	ES/H/0141/001	74980	GP-PHARM S.A.	ES
Lutrate Depot 3,75 mg/2 ml pó e veículo para suspensão injectável de libertação prolongada	ES/H/0141/001	5411301	GP-PHARM S.A.	PT
Leuproreline Lutrate Depot 22,5 mg poeder en oplosmiddel voor suspensie voor injectie met verlengde afgifte	ES/H/0141/002	RVG 115408	GP-PHARM S.A.	NL
Lutrate Depot 22,5 mg prášok a disperzné prostredie na injekčnú suspenziu s predĺženým uvoľňovaním	ES/H/0141/002	56/0262/15-S	ANGELINI PHARMA ÖSTERREICH GMBH	SK
Lutrate Depot 22,5 mg milteliai ir tirpiklis pailginto atpalaidavimo injekcinei suspensijai	ES/H/0141/002	LT/1/12/3051/002	ANGELINI PHARMA ÖSTERREICH GMBH	LT
Lutrate Depot 22,5 mg pulveris un šķīdinātājs ilgstošas darbības injekciju suspensijas pagatavošanai	ES/H/0141/002	15-0156	ANGELINI PHARMA ÖSTERREICH GMBH	LV
Lutrate Depot 22,5 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension	ES/H/0141/002	92440.00.00	GP-PHARM S.A.	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
Lutrate Depot 3,75 mg Prášek a rozpouštědlo pro injekční suspenzi s prodlouženým uvolňováním	ES/H/0141/001	44/616/12-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
Lutrate Depot 3,75 mg, toimeainet prolongeeritult vabastava süstesuspensiooni pulber ja lahusti	ES/H/0141/001	788912	ANGELINI PHARMA ÖSTERREICH GMBH	EE
Lutrate Depot 3,75 mg pulbere şi solvent pentru suspensie injectabilă cu eliberare prelungită	ES/H/0141/001	9333/2016/01	ANGELINI PHARMA ÖSTERREICH GMBH	RO
LUTRATE DEPOT 22,5 mg pulbere şi solvent pentru suspensie injectabilă cu eliberare prelungită	ES/H/0141/002	8162/2015/01	ANGELINI PHARMA ÖSTERREICH GMBH	RO
Lutrate 22,5 mg injektiokuiva-aine ja liuotin depotsuspensiota varten	ES/H/0141/002	32245	GP-PHARM S.A.	FI
Lutrate Depot 22,5 mg pulver og væske til depotinjeksjonsvæske, suspensjon	ES/H/0141/002	14-10087	GP-PHARM S.A.	NO
Lutrate Depot, 22,5 mg, proszek i rozpuszczalnik do sporządzania zawiesiny do wstrzykiwań o przedłużonym uwalnianiu	ES/H/0141/002	22807	ANGELINI PHARMA ÖSTERREICH GMBH	PL
Politrate 22,5 mg polvere e solvente per sospensione iniettabile a rilascio prolungato	ES/H/0141/002	041465028	GP-PHARM S.A.	IT
Lutrate Depot 3,75 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension	ES/H/0141/001	79801.00.00	GP-PHARM S.A.	DE
Politrate Depot 3,75 mg por és oldószer retard szuszpenziós injekcióhoz	ES/H/0141/001	OGYI-T-22202/01	GEDEON RICHTER PLC.	HU
Politrate Depot 22,5 mg por és oldószer retard szuszpenziós injekcióhoz	ES/H/0141/002	OGYI-T-22202/02	GEDEON RICHTER PLC.	HU
Lutrate Depot 22,5 mg κόνις και διαλύτης για παρασκευή ενεσίμου εναιωρήματος παρατεταμένης αποδέσμευσης	ES/H/0141/002	ES/H/0141/002	GP-PHARM S.A.	GR
Politrate Depot 3.75 mg powder and solvent for prolonged-release suspension for injection	ES/H/0141/001	PL 25959/0004	GP-PHARM S.A.	UK
Leuproreline Lutrate Depot 3,75 mg	ES/H/0141/001	RVG 110879	GP-PHARM S.A.	NL

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poeder en oplosmiddel voor suspensie voor injectie met verlengde afgifte				
Lutrate Depot 22,5 mg poeder en oplosmiddel voor suspensie voor injectie met verlengde afgifte	ES/H/0141/002	BE474115	GP-PHARM S.A.	BE
Lutrate Depot 22,5 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension	ES/H/0141/002	BE474115	GP-PHARM S.A.	BE
Lutrate Depot 3,75 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension	ES/H/0141/001	BE432187	GP-PHARM S.A.	BE
Lutrate 22,5 mg pulver och vätska till injektionsvätska, depotsuspension	ES/H/0141/002	32245	GP-PHARM S.A.	FI
Lutrate Depot 3,75 mg pulver og væske til depotinjeksjonsvæske, suspensjon	ES/H/0141/001	11-8703	GP-PHARM S.A.	NO
Politrate 3,75 mg pulver och vätska till injektionsvätska, depotsuspension	ES/H/0141/001	47094	GP-PHARM S.A.	SE
Leuprorelin 1-month Depot 3.75 mg powder and solvent for prolonged-release suspension for injection	ES/H/0141/001	PA1766/001/001	GP-PHARM S.A.	IE
Lutrate Depot 3,75 mg poudre et solvant pour suspension injectable à libération prolongée	ES/H/0141/001	BE432187	GP-PHARM S.A.	BE
Lutrate Depot 3,75 mg прах и разтворител за инжекционна суспензия с удължено освобождаване	ES/H/0141/001/E/001	20120331	ANGELINI PHARMA ÖSTERREICH GMBH	BG
Lutrate Depot 3,75 mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension	ES/H/0141/001	1-31566	ANGELINI PHARMA ÖSTERREICH GMBH	AT
Lutrate 3,75 mg injektiokuiva-aine ja liuotin depotsuspensiota varten	ES/H/0141/001	30283	GP-PHARM S.A.	FI
Lutrate 3,75 mg pulver och vätska till injektionsvätska, depotsuspension	ES/H/0141/001	30283	GP-PHARM S.A.	FI
Lutrate Depot 3,75 mg poeder en oplosmiddel voor suspensie voor injectie met verlengde afgifte	ES/H/0141/001	BE432187	GP-PHARM S.A.	BE

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Lutrate Depot, pulver og solvens til depotinjektionsvæske, suspension	ES/H/0141/001	50966	GP-PHARM S.A.	DK
Lutrate® Depot 3,75 mg κόνις και διαλύτης για παρασκευή ενέσιμου εναιωρήματος παρατεταμένης αποδέσμευσης	ES/H/0141/001	58783	GP-PHARM S.A.	GR
Enanton Depot Dual 11,25 mg pulver och vätska till injektionsvätska, suspension, förfylld spruta	not available	21966	ORION CORPORATION	SE
Enanton Depot Dual 3,75 mg pulver och vätska till injektionsvätska, suspension, förfylld spruta	not available	21965	ORION CORPORATION	SE
Enanton Depot Dual 30 mg pulver och vätska till injektionsvätska, suspension, förfylld spruta	not available	23994	ORION CORPORATION	SE
Enanton Depot Set 3,75 mg, pulver och vätska till injektionsvätska, suspension	not available	21105	ORION CORPORATION	SE
Enanton Depot Set 11,25 mg, pulver och vätska till injektionsvätska, suspension	not available	21106	ORION CORPORATION	SE
Enanton Depot Set 30 mg pulver och vätska till injektionsvätska, suspension	not available	24361	ORION CORPORATION	SE
PROCRIN 1 mg/0,2 ml solución inyectable	not available	57083	ABBVIE SPAIN S.L.U.	ES
Procrin Trimestral 11,25 mg polvo y disolvente para suspensión inyectable en jeringa precargada	not available	74093	ABBVIE SPAIN S.L.U.	ES
Lupron depo 3,75 mg prašak i otapalo za suspenziju za injekciju u napunjenoj štrcaljki	not available	HR-H-336013585	ABBVIE D.O.O. (CROATIA)	HR
Lupron depo 11,25 mg prašak i otapalo za suspenziju za injekciju u napunjenoj štrcaljki	not available	HR-H-880156574	ABBVIE D.O.O. (CROATIA)	HR
ELIGARD 22,5 mg, κόνις και διαλύτης για ενέσιμο διάλυμα	DE/H/4014/001-003/DC	52380/7-7-2016	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
ELIGARD 7,5 mg, κόνις και διαλύτης για ενέσιμο διάλυμα	DE/H/4014/001-003/DC	52379/7-7-2016	ASTELLAS PHARMACEUTICALS A.E.B.E.	GR
ELIPROGEL 45 mg Pulver und	DE/H/4014/003	90920.00.00	ASTELLAS PHARMA EUROPE B.V.	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
Lösungsmittel zur Herstellung einer Injektionslösung				
ELIPROGEL 7,5 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/4014/001	90918.00.00	ASTELLAS PHARMA EUROPE B.V.	DE
ELIPROGEL 22,5 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/4014/002	90919.00.00	ASTELLAS PHARMA EUROPE B.V.	DE
ENANTONE L.P. 3,75 mg, poudre et solvant pour suspension injectable (S.C. ou I.M.) à libération prolongée	not available	34009 375 752 5 6	TAKEDA FRANCE S.A.S.	FR
ELITYRAN®1 Month Depot (DPS) 3.75 mg/PF.SYR. Κόνις και διαλύτης για ενέσιμο εναιώρημα	not available	109199/14	TAKEDA HELLAS S.A.	GR
ELITYRAN®3 Month Depot (DPS) 11.25 mg/PF.SYR. Κόνις και διαλύτης για ενέσιμο εναιώρημα	not available	24831	TAKEDA HELLAS S.A.	GR
Enantone-Gyn Monats-Depot - Zweikammerspritze	not available	1-20236	TAKEDA PHARMA GES.M.B.H.	AT
Trenantone - Zweikammerspritze	not available	1-21532	TAKEDA PHARMA GES.M.B.H.	AT
Enantone Monats-Depot - Zweikammerspritze	not available	1-20237	TAKEDA PHARMA GES.M.B.H.	AT
Sixantone – Zweikammerspritze	not available	1-27558	TAKEDA PHARMA GES.M.B.H.	AT
PROSTAP® 3 DCS 11.25 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled Syringe	not available	PA 1547/3/4	TAKEDA UK LTD	IE
PROSTAP® 6 DCS 30 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-Filled Syringe	not available	PA 1547/3/5	TAKEDA UK LTD	IE
PROSTAP® SR DCS 3.75 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled Syringe	not available	PL 16189/0012	TAKEDA UK LTD	UK
PROSTAP® 3 DCS 11.25 mg Powder and Solvent for Prolonged-release Suspension for Injection in Pre-filled syringe	not available	PL 16189/0013	TAKEDA UK LTD	UK
Enantone® Monats-Depot 3,75 mg	not available	34204.00.00	TAKEDA GMBH (KONSTANZ)	DE

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Retardmikrokapseln und Suspensionsmittel				
Enantone®-Gyn Monats-Depot 3,75 mg Retardmikrokapseln und Suspensionsmittel	not available	39769.00.00	TAKEDA GMBH (KONSTANZ)	DE
ENANTONE Die 1 mg/ 0,2 ml soluzione iniettabile per uso sottocutaneo	not available	027066099	TAKEDA ITALIA S.P.A.	IT
ENANTONE LP 30 mg, poudre et solvant pour suspension injectable (SC) à libération prolongée en seringue pré-remplie	not available	34009 384 583 8 1	TAKEDA FRANCE S.A.S.	FR
ENANTONE L.P. 11,25 mg, microsphères et solution pour usage parentéral (SC ou IM) à libération prolongée	not available	341 254-2	TAKEDA FRANCE S.A.S.	FR
ENANTONE 3,75 mg/ml polvere e solvente per sospensione iniettabile a rilascio prolungato per uso intramuscolare o sottocutaneo	not available	027066125	TAKEDA ITALIA S.P.A.	IT
ENANTONE 11,25 mg/ml polvere e solvente per sospensione iniettabile a rilascio prolungato per uso intramuscolare o sottocutaneo	not available	027066137	TAKEDA ITALIA S.P.A.	IT
Trenantone®-Gyn 11,25 mg Retardmikrokapseln und Suspensionsmitte	not available	46205.00.00	TAKEDA GMBH (KONSTANZ)	DE
Sixantone® 30 mg Retardmikrokapseln und Suspensionsmittel	not available	63660.00.00	TAKEDA GMBH (KONSTANZ)	DE
Klebrocid® Depot Zweikammerspritze 3,75 mg Retardmikrokapseln und Suspensionsmittel	not available	7656.00.01	TAKEDA GMBH (KONSTANZ)	DE
Klebrocid® 3-Monats-Depot 11,25 mg Retardmikrokapseln und Suspensionsmittel	not available	39239.00.00	TAKEDA GMBH (KONSTANZ)	DE
Enantone®-Gyn Monats-Depot 3,75 mg Retardmikrokapseln und Suspensionsmittel	not available	39770.00.00	TAKEDA GMBH (KONSTANZ)	DE
Trenantone®-Gyn 11,25 mg	not available	46206.00.00	TAKEDA GMBH (KONSTANZ)	DE

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Retardmikrokapseln und Suspensionsmittel				
Procrin Semestral 30 mg polvo y disolvente para suspensión inyectable en jeringa precargada	not available	74095	ABBVIE SPAIN S.L.U.	ES
Lucrin Depot 3,75 mg mikrosfery do sporządzania zawiesiny do wstrzykiwań	not available	R/6861	ABBVIE POLSKA SP. Z O.O.	PL
Lucrin Depot, 11,25 mg, mikrosfery do sporządzania zawiesiny do wstrzykiwań	not available	4180	ABBVIE POLSKA SP. Z O.O.	PL
ELIGARD 22,5 mg pulbere şi solvent pentru soluţie injectabilă	not available	6765/2006/01-02	ASTELLAS PHARMA EUROPE B.V.	RO
LUCRIN 5 mg/ml, solution injectable pour voie sous cutanée	not available	34009 328 291 5 6	ABBVIE	FR
LUCRIN 5 mg/ml, solution injectable pour voie sous cutanée	not available	34009 328 292 1 7	ABBVIE	FR
LUCRIN 5 mg/ml, solution injectable pour voie sous cutanée	not available	34009 328 293 8 5	ABBVIE	FR
Eligard 22,5 mg pulver och vätska till injektionsvätska, lösning	DE/H/0508/002	19917	ASTELLAS PHARMA A/S	FI
Eligard 45 mg pulver och vätska till injektionsvätska, lösning	DE/H/0508/003	23432	ASTELLAS PHARMA A/S	FI
Eligard 7,5 mg pulver och vätska till injektionsvätska, lösning	DE/H/0508/001	19916	ASTELLAS PHARMA A/S	FI
DEPO-ELIGARD 45 mg Pulver und Lösungsmittel zur Herstellung von Injektionslösung	DE/H/0508/003	BE314973	ASTELLAS PHARMA B.V., OFFICE BE	BE
DEPO-ELIGARD 7,5 mg Pulver und Lösungsmittel zur Herstellung von Injektionslösung	DE/H/0508/001	BE274032	ASTELLAS PHARMA B.V., OFFICE BE	BE
DEPO-ELIGARD 22,5 mg Pulver und Lösungsmittel zur Herstellung von Injektionslösung	DE/H/0508/002	BE274023	ASTELLAS PHARMA B.V., OFFICE BE	BE
ELIGARD 22,5 mg Prášek a rozpouštědlo pro injekční roztok	DE/H/0508/002	44/078/05-C	ASTELLAS PHARMA S.R.O.	CZ
ЕЛИГАРД 45 mg прах и разтворител за инжекционен разтвор	DE/H/0508/003	20070097	ASTELLAS PHARMA D.O.O.	BG

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
Eligard 45 mg pulbere şi solvent pentru soluţie injectabilă	DE/H/0508/003	4208/2012/01-02-03	ASTELLAS PHARMA EUROPE B.V.	RO
ELIGARD 45 mg Prášek a rozpouštědlo pro injekční roztok	DE/H/0508/003	44/675/07-C	ASTELLAS PHARMA S.R.O.	CZ
ELIGARD 7,5 mg Prášek a rozpouštědlo pro injekční roztok	DE/H/0508/001	44/077/05-C	ASTELLAS PHARMA S.R.O.	CZ
Eligard 22,5 mg por és oldószer oldatos injekcióhoz	DE/H/0508/002	OGYI-T-10010/03	ASTELLAS PHARMA KFT	HU
Eligard 7,5 mg por és oldószer oldatos injekcióhoz	DE/H/0508/001	OGYI-T-10009/04	ASTELLAS PHARMA KFT	HU
DEPO-ELIGARD 45 mg poudre et solvant pour solution injectable	DE/H/0508/003	BE314973	ASTELLAS PHARMA B.V., OFFICE BE	BE
ELIGARD 22,5 mg, stungulyfsstofn og leysir, lausn	DE/H/0508/002	IS/1/04/055/02	ASTELLAS PHARMA A/S	IS
ELIGARD 7,5 mg, stungulyfsstofn og leysir, lausn	DE/H/0508/001	IS/1/04/055/01	ASTELLAS PHARMA A/S	IS
ELIGARD 45 mg, stungulyfsstofn og leysir, lausn	DE/H/0508/003	IS/1/07/041/01	ASTELLAS PHARMA A/S	IS
Eligard Depot 45 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0508/003	1 - 27226	ASTELLAS PHARMA GES.M.B.H.	AT
Eligard Depot 22,5 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	1-25794	ASTELLAS PHARMA GES.M.B.H.	AT
Eligard Depot 7,5 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0508/001	1-25793	ASTELLAS PHARMA GES.M.B.H.	AT
DEPO-ELIGARD 7,5 mg poudre et solvant pour solution injectable	DE/H/0508/001	BE274032	ASTELLAS PHARMA B.V., OFFICE BE	BE
DEPO-ELIGARD 22,5 mg poudre et solvant pour solution injectable	DE/H/0508/002	BE274023	ASTELLAS PHARMA B.V., OFFICE BE	BE
DEPO-ELIGARD 22,5 mg, poeder en oplosmiddel voor oplossing voor injectie	DE/H/0508/002	BE274023	ASTELLAS PHARMA B.V., OFFICE BE	BE
Eligard 7,5 mg poeder en oplosmiddel voor oplossing voor injectie	DE/H/0508/001	RVG 31668	ASTELLAS PHARMA B.V.	NL
Eligard 45 mg poeder en oplosmiddel	DE/H/0508/003	RVG 35313	ASTELLAS PHARMA B.V.	NL

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voor oplossing voor injectie				
ELIGARD® 22,5 mg injektiokuiva-aine ja liuotin, liuosta varten	DE/H/0508/002	19917	ASTELLAS PHARMA A/S	FI
Eligard® 7,5 mg injektiokuiva-aine ja liuotin, liuosta varten	DE/H/0508/001	19916	ASTELLAS PHARMA A/S	FI
ELIGARD 45 mg injektiokuiva-aine ja liuotin, liuosta varten	DE/H/0508/003	23432	ASTELLAS PHARMA A/S	FI
ELIGARD 22,5 mg, poudre et solvant pour solution injectable	DE/H/0508/002	34009 366 902 2 9	ASTELLAS PHARMA SAS	FR
ELIGARD 7,5 mg poudre et solvant pour solution injectable	DE/H/0508/001	34009 366 908 6 8	ASTELLAS PHARMA SAS	FR
Eligard 22,5 mg por és oldószer oldatos injekcióhoz	DE/H/0508/002	OGYI-T-10010/04	ASTELLAS PHARMA KFT	HU
Eligard 45 mg por és oldószer oldatos injekcióhoz	DE/H/0508/003	OGYI-T-10010/08	ASTELLAS PHARMA KFT	HU
Eligard 45 mg por és oldószer oldatos injekcióhoz	DE/H/0508/003	OGYI-T-10010/07	ASTELLAS PHARMA KFT	HU
Eligard 7,5 mg por és oldószer oldatos injekcióhoz	DE/H/0508/001	OGYI-T-10009/03	ASTELLAS PHARMA KFT	HU
Eligard, pulver og solvens til injektionsvæske, opløsning 7,5 mg	DE/H/0508/001	37113	ASTELLAS PHARMA A/S	DK
Eligard, pulver og solvens til injektionsvæske, opløsning 45 mg	DE/H/0508/003	41194	ASTELLAS PHARMA A/S	DK
ELIGARD 22.5 mg powder and solvent for solution for injection	DE/H/0508/002	PA 1241/003/002	ASTELLAS PHARMA CO. LTD.	IE
ELIGARD 7.5 mg, powder and solvent for solution for injection	DE/H/0508/001	PA 1241/003/001	ASTELLAS PHARMA CO. LTD.	IE
ELIGARD 45 mg powder and solvent for solution for injection	DE/H/0508/003	PA 1241/003/003	ASTELLAS PHARMA CO. LTD.	IE
Eligard 22,5 mg poeder en oplosmiddel voor oplossing voor injectie	DE/H/0508/002	RVG 31669	ASTELLAS PHARMA B.V.	NL
ELIGARD 22,5 mg, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań	DE/H/0508/002	11422	ASTELLAS PHARMA SP.Z.O.O.	PL
ELIGARD 7,5 mg, proszek i rozpuszczalnik do sporządzania roztworu do	DE/H/0508/001	11 423	ASTELLAS PHARMA SP.Z.O.O.	PL

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
wstrzykiwań				
ELIGARD 22,5 mg pulver og væske til injeksjonsvæske, oppløsning	DE/H/0508/002	04-2882	ASTELLAS PHARMA A/S	NO
ELIGARD 45 mg pulver og væske til injeksjonsvæske, oppløsning	DE/H/0508/003	07-4995	ASTELLAS PHARMA A/S	NO
ELIGARD 7,5 mg pulver og væske til injeksjonsvæske, oppløsning	DE/H/0508/001	04-2881	ASTELLAS PHARMA A/S	NO
ELIGARD 45 mg, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań	DE/H/0508/003	14 300	ASTELLAS PHARMA SP.Z.O.O.	PL
Eligard 22,5 mg	DE/H/0508/002	56/0010/05-S	ASTELLAS PHARMA S.R.O.	SK
Eligard 45 mg PRÁŠOK A ROZPÚŠŤADLO NA INJEKČNÝ ROZTOK	DE/H/0508/003	56/0473/07-S	ASTELLAS PHARMA S.R.O.	SK
Eligard 7,5 mg prášok a rozpúšťadlo na injekčný roztok	DE/H/0508/001	56/0009/05-S	ASTELLAS PHARMA S.R.O.	SK
ELIGARD 22,5 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0508/002	54786.00.00	ASTELLAS PHARMA EUROPE B.V.	DE
ELIGARD 45 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0508/003	63954.00.00	ASTELLAS PHARMA EUROPE B.V.	DE
ELIGARD 7,5 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0508/001	53653.00.00	ASTELLAS PHARMA EUROPE B.V.	DE
ELIGARD 45 mg milteliai ir tirpiklis injekciniam tirpalui	DE/H/0508/003	LT/1/05/0277/005	ASTELLAS PHARMA EUROPE B.V.	LT
ELIGARD 7,5 mg milteliai ir tirpiklis injekciniam tirpalui	DE/H/0508/001	LT/1/05/0277/001	ASTELLAS PHARMA EUROPE B.V.	LT
ELIGARD 45 mg pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	DE/H/0508/003	07-0345	ASTELLAS PHARMA A/S	LV
ELIGARD 22,5 mg pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	DE/H/0508/002	05-0199	ASTELLAS PHARMA A/S	LV
ELIGARD 7,5 mg pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	DE/H/0508/001	05-0198	ASTELLAS PHARMA A/S	LV
ELIGARD 22,5 mg, pulver och vätska till injektionsvätska, lösning	DE/H/0508/002	21454	ASTELLAS PHARMA A/S	SE
ELIGARD 7,5 mg, pulver och vätska till	DE/H/0508/001	21453	ASTELLAS PHARMA A/S	SE

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injektionsvätska, lösning				
ELIGARD 45 mg, pulver och vätska till injektionsvätska, lösning	DE/H/0508/003	25418	ASTELLAS PHARMA A/S	SE
DEPO-ELIGARD 7,5 mg, poeder en oplosmiddel voor oplossing voor injectie	DE/H/0508/001	BE274032	ASTELLAS PHARMA B.V., OFFICE BE	BE
DEPO-ELIGARD 45 mg, poeder en oplosmiddel voor oplossing voor injectie	DE/H/0508/003	BE314973	ASTELLAS PHARMA B.V., OFFICE BE	BE
ELIGARD MENSUAL 7,5 mg, polvo y disolvente para solución inyectable	DE/H/0508/001	66.620	ASTELLAS PHARMA S.A.	ES
ELIGARD SEMESTRAL 45 mg polvo y disolvente para solución inyectable	DE/H/0508/003	69.357	ASTELLAS PHARMA S.A.	ES
ELIGARD TRIMESTRAL 22,5 mg polvo y disolvente para solución inyectable	DE/H/0508/002	66.627	ASTELLAS PHARMA S.A.	ES
ELIGARD 22,5 mg milteliai ir tirpiklis injekciniam tirpalui	DE/H/0508/002	N1 - LT/1/05/0277/003	ASTELLAS PHARMA EUROPE B.V.	LT
ELIGARD 45 mg polvere e solvente per soluzione iniettabile	DE/H/0508/003	036967053/M	ASTELLAS PHARMA S.P.A.	IT
ELIGARD 45 mg poudre et solvant pour solution injectable	DE/H/0508/003	34009 382 633 8 1	ASTELLAS PHARMA SAS	FR
ELIGARD 7,5 mg poudre et solvant pour solution injectable	DE/H/0508/001	34009 566 565 5 4	ASTELLAS PHARMA SAS	FR
ELIGARD, 45 mg süstelahuse pulber ja lahusti	DE/H/0508/003	557507	ASTELLAS PHARMA A/S	EE
ELIGARD, 7,5 mg süstelahuse pulber ja lahusti	DE/H/0508/001	466005	ASTELLAS PHARMA A/S	EE
ELIGARD, 22,5 mg süstelahuse pulber ja lahusti	DE/H/0508/002	465905	ASTELLAS PHARMA A/S	EE
Eligard, pulver og solvens til injektionsvæske, opløsning 22,5 mg	DE/H/0508/002	37114	ASTELLAS PHARMA A/S	DK
ELIGARD® 45 mg, κόνις και διαλύτης για ενέσιμο διάλυμα	DE/H/0508/003	20460	ASTELLAS PHARMACEUTICALS A.E.B.E.	CY
ELIGARD 22,5 mg, κόνις και διαλύτης για ενέσιμο διάλυμα	DE/H/0508/002	19686	ASTELLAS PHARMACEUTICALS A.E.B.E.	CY
ELIGARD 7,5 mg, κόνις και διαλύτης για ενέσιμο διάλυμα	DE/H/0508/001	19687	ASTELLAS PHARMACEUTICALS A.E.B.E.	CY
ELIGARD 22,5 mg, poudre et solvant pour	DE/H/0508/002	34009 566 566 1 5	ASTELLAS PHARMA SAS	FR

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solution injectable				
ELIGARD 45 mg poudre et solvant pour solution injectable	DE/H/0508/003	34009 382 635 0 3	ASTELLAS PHARMA SAS	FR
ELIGARD 45 mg milteliai ir tirpiklis injekciniam tirpalui	DE/H/0508/003	LT/1/05/0277/006	ASTELLAS PHARMA EUROPE B.V.	LT
DEPO-ELIGARD 45 mg poudre et solvant pour solution injectable	DE/H/0508/003	0566/07110035	ASTELLAS PHARMA B.V., OFFICE BE	LU
DEPO-ELIGARD 22,5 mg poudre et solvant pour solution injectable	DE/H/0508/002	0566/05068254	ASTELLAS PHARMA B.V., OFFICE BE	LU
DEPO-ELIGARD 7,5 mg poudre et solvant pour solution injectable	DE/H/0508/001	0566/05068253	ASTELLAS PHARMA B.V., OFFICE BE	LU
ELIGARD 7,5 mg milteliai ir tirpiklis injekciniam tirpalui	DE/H/0508/001	LT/1/05/0277/002	ASTELLAS PHARMA EUROPE B.V.	LT
ELIGARD 22,5 mg pó e solvente para solução injectável	DE/H/0508/002	5469689	ASTELLAS FARMA LDA.	PT
ELIGARD 7,5 mg pó e solvente para solução injectável	DE/H/0508/001	5469481	ASTELLAS FARMA LDA.	PT
ELIGARD 45 mg pó e solvente para solução injectável	DE/H/0508/003	5062336	ASTELLAS FARMA LDA.	PT
ELIGARD 22,5 mg milteliai ir tirpiklis injekciniam tirpalui	DE/H/0508/002	N2 - LT/1/05/0277/004	ASTELLAS PHARMA EUROPE B.V.	LT
ELIGARD 45 mg pó e solvente para solução injectável	DE/H/0508/003	5062344	ASTELLAS FARMA LDA.	PT
ELIGARD 22,5 mg pó e solvente para solução injectável	DE/H/0508/002	5469788	ASTELLAS FARMA LDA.	PT
ELIGARD 7,5 mg pó e solvente para solução injectável	DE/H/0508/001	5469580	ASTELLAS FARMA LDA.	PT
ELIGARD 45 mg polvere e solvente per soluzione iniettabile	DE/H/0508/003	36967065	ASTELLAS PHARMA S.P.A.	IT
ELIGARD 22,5 mg polvere e solvente per soluzione iniettabile	DE/H/0508/002	36967040	ASTELLAS PHARMA S.P.A.	IT
ELIGARD 7,5 mg polvere e solvente per soluzione iniettabile	DE/H/0508/001	036967038	ASTELLAS PHARMA S.P.A.	IT
ELIGARD 7,5 mg prašek in vehikel za raztopino za injiciranje	DE/H/0508/001	H/05/00537/001-002	ASTELLAS PHARMA D.O.O.	SI
ELIGARD 45 mg prašek in vehikel za	DE/H/0508/003	H/05/00537/005-006	ASTELLAS PHARMA D.O.O.	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
raztopino za injiciranje				
ELIGARD 22,5 mg prašek in vehikel za raztopino za injiciranje	DE/H/0508/002	H/05/00537/003-004	ASTELLAS PHARMA D.O.O.	SI