



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2020
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: galantamine

Procedure no.: PSUSA/00001512/202003

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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
Luventa XL 16 mg prolonged-release capsules, hard	not available	PL 42924/0002	FONTUS HEALTH	UK
Luventa XL 16 mg prolonged-release capsules, hard	not available	PL 42924/0002	FONTUS HEALTH	UK
Luventa XL 24 mg prolonged-release capsules, hard	not available	PL 42924/0003	FONTUS HEALTH	UK
Luventa XL 24 mg prolonged-release capsules, hard	not available	PL 42924/0003	FONTUS HEALTH	UK
Luventa XL 8 mg prolonged-release capsules, hard	not available	PL 42924/0001	FONTUS HEALTH	UK
Luventa XL 8 mg prolonged-release capsules, hard	not available	PL 42924/0001	FONTUS HEALTH	UK
Reminyl	SE/H/0210/ 004	31526	JANSSEN-CILAG A/S	DK
REMINYL 16 mg gélules à libération prolongée	SE/H/0210/006	0162/08099966	JANSSEN-CILAG NV	LU
REMINYL 16 mg gélules à libération prolongée	SE/H/0210/006	0162/08099966	JANSSEN-CILAG NV	LU

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REMINYL 24 mg gélules à libération prolongée	SE/H/0210/007	0162/08099967	JANSSEN-CILAG NV	LU
REMINYL 8 mg + 16 mg gélules à libération prolongée (emballage de départ)	SE/H/0210/ 008	0162/08099968	JANSSEN-CILAG NV	LU
REMINYL 8 mg gélules à libération prolongée	SE/H/0210/005	0162/10080824	JANSSEN-CILAG NV	LU
REMINYL 8 mg gélules à libération prolongée	SE/H/0210/005	0162/10080824	JANSSEN-CILAG NV	LU
REMINYL 1 x täglich 16 mg Hartkapseln, retardiert	SE/H/0210/ 006	49531.01.02	JANSSEN-CILAG GMBH	DE
REMINYL 1 x täglich 24 mg Hartkapseln, retardiert	SE/H/0210/ 007	49531.02.02	JANSSEN-CILAG GMBH	DE
REMINYL 1 x täglich 8 mg Hartkapseln, retardiert	SE/H/0210/ 005	49531.00.02	JANSSEN-CILAG GMBH	DE
REMINYL 16 mg cápsulas de libertação prolongada	SE/H/0210/ 006	5269881	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 16 mg cápsulas de libertação prolongada	SE/H/0210/ 006	5269980	JANSSEN-CILAG FARMACÊUTICA, 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
REMINYL 16 mg cápsulas de libertação prolongada	SE/H/0210/ 006	5269782	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 16 mg cápsulas de libertação prolongada	SE/H/0210/ 006	5269683	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 16 mg capsule rigide a rilascio prolungato	SE/H/0210/006	034752131	JANSSEN-CILAG SPA	IT
REMINYL 16 mg capsule rigide a rilascio prolungato	SE/H/0210/006	034752168/M	JANSSEN-CILAG SPA	IT
REMINYL 16 mg capsule rigide a rilascio prolungato	SE/H/0210/006	034752143/M	JANSSEN-CILAG SPA	IT
REMINYL 16 mg capsule rigide a rilascio prolungato	SE/H/0210/006	034752156/M	JANSSEN-CILAG SPA	IT
Reminyl 16 mg depotkapsel, hard	SE/H/0210/006	04-2775	JANSSEN-CILAG A/S	NO
REMINYL 16 mg depotkapseli, kova	SE/H/0210/006	19633	JANSSEN-CILAG OY	FI
REMINYL 16 mg depotkapslar, hårda	SE/H/0210/006	19349	JANSSEN-CILAG 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
REMINYL 16 mg harde capsules met verlengde afgifte	SE/H/0210/006	BE269464	JANSSEN-CILAG NV	BE
REMINYL 16 mg harde capsules met verlengde afgifte	SE/H/0210/006	BE269455	JANSSEN-CILAG NV	BE
Reminyl 16 mg Retardkapseln	SE/H/0210/006	1-25738	JANSSEN-CILAG PHARMA GMBH	AT
REMINYL 16 mg trde kapsule s podaljšaním sproščanjem	not available	H/06/01336/002	JOHNSON & JOHNSON D.O.O.	SI
REMINYL 16 mg καψάκια παρατεταμένης αποδέσμευσης, σκληρά	SE/H/0210/ 006	31822/12-5-2015	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
REMINYL 16 mg cápsulas duras de liberación prolongada	SE/H/0210/ 006	66.651	JANSSEN-CILAG S.A.	ES
REMINYL 24 mg cápsulas de libertação prolongada	SE/H/0210/ 007	5270186	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 24 mg cápsulas de libertação prolongada	SE/H/0210/ 007	5270285	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 24 mg cápsulas de libertação prolongada	SE/H/0210/ 007	5270384	JANSSEN-CILAG FARMACÊUTICA, 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
REMINYL 24 mg cápsulas de libertação prolongada	SE/H/0210/ 007	5270087	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 24 mg cápsulas duras de liberación prolongada	SE/H/0210/ 007	66.652	JANSSEN-CILAG S.A.	ES
REMINYL 24 mg capsule rigide a rilascio prolungato	SE/H/0210/007	034752170	JANSSEN-CILAG SPA	IT
REMINYL 24 mg capsule rigide a rilascio prolungato	SE/H/0210/007	034752182/M	JANSSEN-CILAG SPA	IT
REMINYL 24 mg capsule rigide a rilascio prolungato	SE/H/0210/007	034752194/M	JANSSEN-CILAG SPA	IT
REMINYL 24 mg capsule rigide a rilascio prolungato	SE/H/0210/007	034752206/M	JANSSEN-CILAG SPA	IT
Reminyl 24 mg depotkapsel, hard	SE/H/0210/007	04-2776	JANSSEN-CILAG A/S	NO
REMINYL 24 mg depotkapseli, kova	SE/H/0210/007	19634	JANSSEN-CILAG OY	FI
REMINYL 24 mg depotkapslar, hårda.	SE/H/0210/007	19350	JANSSEN-CILAG 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
REMINYL 24 mg gélules à libération prolongée	SE/H/0210/007	0162/08099967	JANSSEN-CILAG NV	LU
REMINYL 24 mg gélules à libération prolongée	SE/H/0210/007	0162/08099967	JANSSEN-CILAG NV	LU
REMINYL 24 mg harde capsules met verlengde afgifte	SE/H/0210/007	BE269473	JANSSEN-CILAG NV	BE
REMINYL 24 mg harde capsules met verlengde afgifte	SE/H/0210/007	BE269482	JANSSEN-CILAG NV	BE
Reminyl 24 mg Retardkapseln	SE/H/0210/007	1-25739	JANSSEN-CILAG PHARMA GMBH	AT
REMINYL 24 mg trde kapsule s podaljšanim sproščanjem	not available	H/06/01336/003	JOHNSON & JOHNSON D.O.O.	SI
REMINYL 24 mg καψάκια παρατεταμένης αποδέσμευσης, σκληρά	SE/H/0210/ 007	31823/12-5-2015	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
REMINYL 4 mg/ml drank	SE/H/0210/ 004	BE217052	JANSSEN-CILAG NV	BE
REMINYL 4 mg/ml Lösung zum Einnehmen	SE/H/0210/ 004	1-23750	JANSSEN-CILAG PHARMA GMBH	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
REMINYL 4 mg/ml Lösung zum Einnehmen	SE/H/0210/ 004	49531.00.01	JANSSEN-CILAG GMBH	DE
Reminyl 4 mg/ml mikstur, oppløsning	SE/H/0210/ 004	MTNR. 00-2146	JANSSEN-CILAG A/S	NO
REMINYL 4 mg/ml oraaliliuos	SE/H/0210/ 004	15676	JANSSEN-CILAG OY	FI
REMINYL 4 mg/ml oral lösning.	SE/H/0210/ 004	15565	JANSSEN-CILAG AB	SE
REMINYL 4 mg/ml oral solution	not available	19543	JANSSEN-CILAG INTERNATIONAL NV	CY
REMINYL 4 mg/ml oral solution	SE/H/0210/004	PA1575/003/001	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL 4 mg/ml oral solution	not available	018/00104	JANSSEN-CILAG INTERNATIONAL NV	MT
REMINYL 4 mg/ml oral solution	SE/H/0210/004	PL 08557/0042	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL 4 mg/ml solução oral	SE/H/0210/ 004	3418183	JANSSEN-CILAG FARMACÊUTICA, 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
REMINYL 4 mg/ml solución oral	SE/H/0210/ 004	63.388	JANSSEN-CILAG S.A.	ES
REMINYL 4 mg/ml solution buvable	SE/H/0210/ 004	0162/10080823	JANSSEN-CILAG NV	LU
REMINYL 4 mg/ml soluzione orale	SE/H/0210/ 004	034752079	JANSSEN-CILAG SPA	IT
REMINYL 4 mg/ml πόσιμο διάλυμα	SE/H/0210/ 004	31820/12-5-2015	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
Reminyl 4 mg/ml, soluție orală	not available	4535/2004/01	JANSSEN PHARMACEUTICA NV	RO
REMINYL 4 mg/ml, solution buvable	SE/H/0210/ 004	34009 355 372 2 5	JANSSEN-CILAG	FR
REMINYL 8 mg + 16 mg capsule rigide a rilascio prolungato (confezione di inizio terapia)	SE/H/0210/ 008	034752218	JANSSEN-CILAG SPA	IT
REMINYL 8 mg + 16 mg depotkapseli, kova (aloituspakkaus)	SE/H/0210/ 008	19635	JANSSEN-CILAG OY	FI
REMINYL 8 mg + 16 mg depotkapslar, hårda (upptrappningsförpacknin g).	SE/H/0210/ 008	19351	JANSSEN-CILAG 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
REMINYL 8 mg + 16 mg harde capsules met verlengde afgifte (startverpakking)	SE/H/0210/ 008	BE269437	JANSSEN-CILAG NV	BE
Reminyl 8 mg + 16 mg Retardkapseln (Startpackung)	SE/H/0210/ 008	1-25740	JANSSEN-CILAG PHARMA GMBH	AT
REMINYL 8 mg + 16 mg καψάκια παρατεταμένης αποδέσμευσης, σκληρά (συσκευασία έναρξης θεραπείας)	SE/H/0210/ 008	31824/12-05-2015	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
REMINYL 8 mg cápsulas de libertação prolongada	SE/H/0210/ 005	5269485	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 8 mg cápsulas de libertação prolongada	SE/H/0210/ 005	5269584	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 8 mg cápsulas de libertação prolongada	SE/H/0210/ 005	5269386	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
REMINYL 8 mg capsule rigide a rilascio prolungato	SE/H/0210/005	034752117	JANSSEN-CILAG SPA	IT
REMINYL 8 mg capsule rigide a rilascio prolungato	SE/H/0210/005	034752129/M	JANSSEN-CILAG SPA	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
REMINYL 8 mg capsule rigide a rilascio prolungato	SE/H/0210/005	034752105/M	JANSSEN-CILAG SPA	IT
Reminyl 8 mg depotkapsel, hard	SE/H/0210/005	04-2774	JANSSEN-CILAG A/S	NO
REMINYL 8 mg depotkapseli, kova	SE/H/0210/005	19632	JANSSEN-CILAG OY	FI
REMINYL 8 mg depotkapslar, hårda.	SE/H/0210/005	19348	JANSSEN-CILAG AB	SE
REMINYL 8 mg harde capsules met verlengde afgifte	SE/H/0210/005	BE269446	JANSSEN-CILAG NV	BE
REMINYL 8 mg harde capsules met verlengde afgifte	SE/H/0210/005	BE269421	JANSSEN-CILAG NV	BE
Reminyl 8 mg Retardkapseln	SE/H/0210/005	1-25737	JANSSEN-CILAG PHARMA GMBH	AT
REMINYL 8 mg trde kapsule s podaljšanim sproščanjem	not available	H/06/01336/001	JOHNSON & JOHNSON D.O.O.	SI
REMINYL 8 mg καψάκια παρατεταμένης αποδέσμευσης, σκληρά	SE/H/0210/ 005	31821/12-05-2015	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR

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REMINYL 8 mg cápsulas duras de liberación prolongada	SE/H/0210/ 005	66.650	JANSSEN-CILAG S.A.	ES
REMINYL 8mg + 16mg cápsulas de libertação prolongada (embalagem inicial)	SE/H/0210/ 008	5270483	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
Reminyl Startpakning 8 mg 28 stk depotkapsel, hard + 16 mg 28 stk depotkapsler, hard	SE/H/0210/ 008	04-2777	JANSSEN-CILAG A/S	NO
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PA1575/003/006	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PA1575/003/006	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PA1575/003/006	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PA1575/003/006	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PA1575/003/006	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PL 08557/0053	SHIRE PHARMACEUTICALS LIMITED	UK

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REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PL 08557/0053	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PL 08557/0053	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PL 08557/0053	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 16 mg prolonged-release capsules, hard	SE/H/0210/006	PL 08557/0053	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 24 mg prolonged-release capsules, hard	SE/H/0210/007	PL 08557/0054	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 24 mg prolonged-release capsules, hard	SE/H/0210/007	PL 08557/0054	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 24 mg prolonged-release capsules, hard	SE/H/0210/007	PL 08557/0054	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 24 mg prolonged-release capsules, hard	SE/H/0210/007	PL 08557/0054	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 24 mg prolonged-release capsules, hard	SE/H/0210/007	PL 08557/0054	SHIRE PHARMACEUTICALS LIMITED	UK

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
REMINYL XL 24 mg prolonged-release capsules, hard.	SE/H/0210/007	PA1575/003/007	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 24 mg prolonged-release capsules, hard.	SE/H/0210/007	PA1575/003/007	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 24 mg prolonged-release capsules, hard.	SE/H/0210/007	PA1575/003/007	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 24 mg prolonged-release capsules, hard.	SE/H/0210/007	PA1575/003/007	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 24 mg prolonged-release capsules, hard.	SE/H/0210/007	PA1575/003/007	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 8 mg prolonged-release capsules, hard	SE/H/0210/005	PA1575/003/005	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 8 mg prolonged-release capsules, hard	SE/H/0210/005	PA1575/003/005	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 8 mg prolonged-release capsules, hard	SE/H/0210/005	PA1575/003/005	SHIRE PHARMACEUTICALS IRELAND LIMITED	IE
REMINYL XL 8 mg prolonged-release capsules, hard	SE/H/0210/005	PL 08557/0052	SHIRE PHARMACEUTICALS LIMITED	UK

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
REMINYL XL 8 mg prolonged-release capsules, hard	SE/H/0210/005	PL 08557/0052	SHIRE PHARMACEUTICALS LIMITED	UK
REMINYL XL 8 mg prolonged-release capsules, hard	SE/H/0210/005	PL 08557/0052	SHIRE PHARMACEUTICALS LIMITED	UK
Reminyl, hårde depotkapsler	SE/H/0210/006	36815	JANSSEN-CILAG A/S	DK
Reminyl, hårde depotkapsler	SE/H/0210/005	36814	JANSSEN-CILAG A/S	DK
Reminyl, hårde depotkapsler	SE/H/0210/007	36816	JANSSEN-CILAG A/S	DK