30 September 2021
EMA/382258/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: baclofen (intrathecal)

Procedure no.: PSUSA/00000293/202101

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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
Baclofen "Sintetica", infusionsvæske, opløsning 0,5 mg/ml	BE/H/0152/002	59288	SINTETICA GMBH	DK
Baclofen "Sintetica", infusionsvæske, opløsning 2 mg/ml	BE/H/0152/003	59289	SINTETICA GMBH	DK
Baclofen "Sintetica", injektionsvæske, opløsning	BE/H/0152/001	59287	SINTETICA GMBH	DK
Baclofen Aguettant 0,05 mg/mL solution for injection	BE/H/0152/001/DC	PL 14434/0024	LABORATOIRE AGUETTANT	XI
Baclofen Aguettant 0.05mg/ml solution for injection	BE/H/0152/001/DC	PL 14434/0024	LABORATOIRE AGUETTANT	XI
Baclofen Aguettant 0.5mg/ml solution for infusion	BE/H/0152/002/DC	PL 14434/0027	LABORATOIRE AGUETTANT	XI
Baclofen Aguettant 2 mg/mL solution for infusion	BE/H/0152/003/DC	PL 14434/0026	LABORATOIRE AGUETTANT	XI
Baclofen Aguettant 2 mg/mL solution for infusion	BE/H/0152/003/DC	PL 14434/0026	LABORATOIRE AGUETTANT	XI
Baclofen Aguettant 2 mg/mL solution for infusion	BE/H/0152/003/DC	PL 14434/0026	LABORATOIRE AGUETTANT	XI

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
Baclofen Aguettant 2 mg/ml solution for infusion	BE/H/0152/003/DC	PL 14434/0026	LABORATOIRE AGUETTANT	XI
Baclofen Aguettant Intrathecal 0,05 mg/1 ml, oplossing voor injectie	BE/H/0152/001/DC	BE384483	LABORATOIRE AGUETTANT	BE
Baclofen Aguettant Intrathecal 0,05 mg/1ml, oplossing voor injectie	BE/H/0152/001/DC	BE384483	LABORATOIRE AGUETTANT	BE
Baclofen Aguettant Intrathecal 10mg/20ml, solution pour perfusion	BE/H/0152/002/DC	BE384517	LABORATOIRE AGUETTANT	BE
Baclofen Aguettant Intrathecal 10mg/5ml, solution pour perfusion	BE/H/0152/003	BE384492	LABORATOIRE AGUETTANT	BE
Baclofen Aguettant Intrathecal 10mg/5ml, solution pour perfusion	BE/H/0152/003	BE384492	LABORATOIRE AGUETTANT	BE
Baclofen Aguettant Intrathecal 10mg/5ml, solution pour perfusion	BE/H/0152/003	BE384492	LABORATOIRE AGUETTANT	BE
Baclofen Aguettant Intrathecal 40mg/20ml, solution pour perfusion	BE/H/0152/003	BE384501	LABORATOIRE AGUETTANT	BE
Baclofen Meduna 0,05 mg/ml Intrathekal Injektionslösung	BE/H/0152/001	1-29979	SINTETICA 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
Baclofen Meduna 0,5 mg/ml Intrathekal Infusionslösung	BE/H/0152/002	1-29980	SINTETICA GMBH	AT
Baclofen Meduna 2 mg/ml Intrathekal Infusionslösung	BE/H/0152/003	1-29981	SINTETICA GMBH	AT
Baclofen Sintetica 0,05 mg/ml injekční roztok	BE/H/0152/001	63/098/17-C	SINTETICA GMBH	CZ
Baclofen Sintetica 0,05 mg/ml injekčný roztok	BE/H/0152/001	63/0137/18-S	SINTETICA GMBH	SK
Baclofen Sintetica 0,05 mg/ml injeksjonsvæske, oppløsning	BE/H/0152/001	17-11622	SINTETICA GMBH	NO
Baclofen Sintetica 0,05 mg/ml oldatos injekció	BE/H/0152/001	OGYI-T-23358/01	SINTETICA GMBH	HU
Baclofen Sintetica 0,05 mg/ml oldatos injekció	BE/H/0152/001	OGYI-T-23358/02	SINTETICA GMBH	HU
Baclofen Sintetica 0,05 mg/ml šķīdums injekcijām	BE/H/0152/001	18-0001	SINTETICA GMBH	LV
Baclofen Sintetica 0,05 mg/ml süstelahus	BE/H/0152/001	964118	SINTETICA GMBH	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
Baclofen Sintetica 0,5 mg/ml infusionsvätska, lösning	BE/H/0152/002	56177	SINTETICA GMBH	SE
Baclofen Sintetica 0,5 mg/ml infusioonilahus	BE/H/0152/002	964218	SINTETICA GMBH	EE
Baclofen Sintetica 0,5 mg/ml infusjonsvæske, oppløsning	BE/H/0152/002	17-11623	SINTETICA GMBH	NO
Baclofen Sintetica 0,5 mg/ml infuzinis tirpalas	BE/H/0152/002	LT/1/18/4180/003	SINTETICA GMBH	LT
Baclofen Sintetica 0,5 mg/ml infuzní roztok	BE/H/0152/002	63/099/17-C	SINTETICA GMBH	CZ
Baclofen Sintetica 0,5 mg/ml infúzny roztok	BE/H/0152/002	63/0138/18-S	SINTETICA GMBH	SK
Baclofen Sintetica 0,5 mg/ml oldatos infúzió	BE/H/0152/002	OGYI-T-23358/03	SINTETICA GMBH	HU
Baclofen Sintetica 0,5 mg/ml šķīdums infūzijām	BE/H/0152/002	18-0002	SINTETICA GMBH	LV
Baclofen Sintetica 2 mg/ml Infusionslösung	BE/H/0152/003	78469.00.00	SINTETICA GMBH	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
Baclofen Sintetica 2 mg/ml infusionsvätska, lösning	BE/H/0152/003	56178	SINTETICA GMBH	SE
Baclofen Sintetica 2 mg/ml infusioonilahus	BE/H/0152/003	964318	SINTETICA GMBH	EE
Baclofen Sintetica 2 mg/ml infusjonsvæske, oppløsning	BE/H/0152/003	17-11624	SINTETICA GMBH	NO
Baclofen Sintetica 2 mg/ml infuzinis tirpalas	BE/H/0152/003	LT/1/18/4180/004	SINTETICA GMBH	LT
Baclofen Sintetica 2 mg/ml infuzinis tirpalas	BE/H/0152/003	LT/1/18/4180/006	SINTETICA GMBH	LT
Baclofen Sintetica 2 mg/ml infuzinis tirpalas	BE/H/0152/003	LT/1/18/4180/005	SINTETICA GMBH	LT
Baclofen Sintetica 2 mg/ml infuzinis tirpalas	BE/H/0152/003	LT/1/18/4180/007	SINTETICA GMBH	LT
Baclofen Sintetica 2 mg/ml infuzní roztok	BE/H/0152/003	63/100/17-C	SINTETICA GMBH	CZ
Baclofen Sintetica 2 mg/ml infúzny roztok	BE/H/0152/003	63/0139/18-S	SINTETICA GMBH	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
Baclofen Sintetica 2 mg/ml oldatos infúzió	BE/H/0152/003	OGYI-T-23358/04	SINTETICA GMBH	HU
Baclofen Sintetica 2 mg/ml oldatos infúzió	BE/H/0152/003	OGYI-T-23358/05	SINTETICA GMBH	HU
Baclofen Sintetica 2 mg/ml oldatos infúzió	BE/H/0152/003	OGYI-T-23358/06	SINTETICA GMBH	HU
Baclofen Sintetica 2 mg/ml oldatos infúzió	BE/H/0152/003	OGYI-T-23358/07	SINTETICA GMBH	HU
Baclofen Sintetica 2 mg/ml šķīdums infūzijām	BE/H/0152/003	18-0003	SINTETICA GMBH	LV
Baclofen Sintetica 50 mikrogram/ml injektionsvätska, lösning	BE/H/0152/001	56176	SINTETICA GMBH	SE
Baclofen Sintetica 50 mikrogramų/ml injekcinis tirpalas	BE/H/0152/001	LT/1/18/4180/001	SINTETICA GMBH	LT
Baclofen Sintetica 50 mikrogramų/ml injekcinis tirpalas	BE/H/0152/001	LT/1/18/4180/002	SINTETICA GMBH	LT
Baclofen Sintetica í mænuvökva, 0,05 mg/ml stungulyf, lausn	BE/H/0152/001	IS/1/17/086/01	SINTETICA GMBH	IS

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
Baclofen Sintetica í mænuvökva, 0,5 mg/ml Innrennslislyf, lausn	BE/H/0152/002	IS/1/17/086/02	SINTETICA GMBH	IS
Baclofen Sintetica í mænuvökva, 2 mg/ml innrennslislyf, lausn	BE/H/0152/003	IS/1/17/086/03	SINTETICA GMBH	IS
Baclofen Sintetica Intrathecaal 0,05 mg/ml oplossing voor injectie	BE/H/0152/001	RVG 120888	SINTETICA GMBH	NL
Baclofen Sintetica Intrathecaal 0,5 mg/ml oplossing voor infusie	BE/H/0152/002	RVG 120889	SINTETICA GMBH	NL
Baclofen Sintetica Intrathecaal 2 mg/ml oplossing voor infusie	BE/H/0152/003	RVG 120890	SINTETICA GMBH	NL
Baclofen Sintetica Intrathekal 0,05 mg/ml Injektionslösung	BE/H/0152/001	78168.00.00	SINTETICA GMBH	DE
Baclofen Sintetica Intrathekal 0,5 mg/ml Infusionslösung	BE/H/0152/002	78468.00.00	SINTETICA GMBH	DE
Baclofen Sintetica, 0,05 mg/1 ml, roztwór do wstrzykiwan	BE/H/0152/001	25679	SINTETICA GMBH	PL
Baclofen Sintetica, 0,05 mg/ml injektioneste, liuos	BE/H/0152/001	35086	SINTETICA GMBH	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
Baclofen Sintetica, 0,5 mg/ml (10 mg/20 ml), roztwór do infuzji	BE/H/0152/002	25680	SINTETICA GMBH	PL
Baclofen Sintetica, 0,5 mg/ml infuusioneste, liuos	BE/H/0152/002	35087	SINTETICA GMBH	FI
Baclofen Sintetica, 2 mg/ml (10 mg/5 ml; 40 mg/20 ml), roztwór do infuzji	BE/H/0152/003	25681	SINTETICA GMBH	PL
Baclofen Sintetica, 2 mg/ml infuusioneste, liuos	BE/H/0152/003	35088	SINTETICA GMBH	FI
Baclofen SUN 0,05 mg/1 ml Injektionslösung	DE/H/1322/001	70824.00.00	SUN PHARMACEUTICALS GERMANY GMBH	DE
Baclofen SUN 10 mg/20 ml Infusionslösung	DE/H/1322/002	70825.00.00	SUN PHARMACEUTICALS GERMANY GMBH	DE
Baclofen SUN 10 mg/5 ml Infusionslösung	DE/H/1322/003	70826.00.00	SUN PHARMACEUTICALS GERMANY GMBH	DE
Baclofen/Sintetica 0,05 mg/ml ενέσιμο διάλυμα	BE/H/0152/001	27813/17/18-04-2018	SINTETICA GMBH	GR
Baclofen/Sintetica 0,5 mg/ml διάλυμα για έγχυση	BE/H/0152/002	27822/17/18-04-2018	SINTETICA GMBH	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
Baclofen/Sintetica 2 mg/ml διάλυμα για έγχυση	BE/H/0152/003	27825/17/18-04-2018	SINTETICA GMBH	GR
BACLOFENE AGUETTANT 0,05 mg/ml, solution injectable pour voie intrathécale en ampoule	BE/H/152/01/DC	34009 578 675 5 3	LABORATOIRE AGUETTANT	FR
BACLOFENE AGUETTANT 0,05 mg/ml, solution injectable pour voie intrathécale en ampoule	BE/H/152/01/DC	34009 550 019 8 0	LABORATOIRE AGUETTANT	FR
BACLOFENE AGUETTANT 0,5 mg/ml, solution pour perfusion pour voie intrathécale en ampoule	BE/H/152/02/DC	34009 578 674 9 2	LABORATOIRE AGUETTANT	FR
BACLOFENE AGUETTANT 2 mg/ml, solution pour perfusion pour voie intrathécale en ampoule	BE/H/152/03/DC	34009 578 672 6 3	LABORATOIRE AGUETTANT	FR
BACLOFENE AGUETTANT 2 mg/ml, solution pour perfusion pour voie intrathécale en ampoule	BE/H/152/03/DC	34009 578 673 2 4	LABORATOIRE AGUETTANT	FR
BACLOFENE AGUETTANT 2 mg/ml, solution pour perfusion pour voie intrathécale en ampoule	BE/H/152/03/DC	34009 550 019 9 7	LABORATOIRE AGUETTANT	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
BACLOFENE AGUETTANT 2 mg/ml, solution pour perfusion pour voie intrathécale en ampoule	BE/H/152/03/DC	34009 550 708 9 4	LABORATOIRE AGUETTANT	FR
BACLOFENE BIOINDUSTRIA L.I.M. 0,05 mg/1 ml soluzione iniettabile per uso intratecale	not available	041650033	BIOINDUSTRIA LIM LABORATORIO ITALIANO MEDICINALI SPA	IT
BACLOFENE BIOINDUSTRIA L.I.M. 10 mg/20 ml soluzione iniettabile per uso intratecale	not available	041650019	BIOINDUSTRIA LIM LABORATORIO ITALIANO MEDICINALI SPA	IT
BACLOFENE BIOINDUSTRIA L.I.M. 10 mg/5 ml soluzione iniettabile per uso intratecale	not available	041650021	BIOINDUSTRIA LIM LABORATORIO ITALIANO MEDICINALI SPA	IT
Baclofene Molteni 10 mg/5 ml soluzione per infusione	BE/H/0152/003	040646061	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
Baclofene Molteni 10 mg/5 ml soluzione per infusione	BE/H/0152/003	040646034	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
Baclofene Molteni 40 mg/20 ml soluzione per infusione	BE/H/0152/003	040646046	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	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
Baclofene Molteni 0,05 mg/1 ml soluzione iniettabile	BE/H/0152/001	040646059	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
Baclofene Molteni 0,05 mg/1 ml soluzione iniettabile	BE/H/0152/001	040646010	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
Baclofene Molteni 10 mg/20 ml soluzione per infusione	BE/H/0152/002	040646022	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
Baclofene Molteni 10 mg/5 ml soluzione per infusione	BE/H/0152/003	040646073	L. MOLTENI AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
BACLOFENE SUN 0,05 mg/ml, solution injectable	DE/H/1322/001	34009 576 806 5 7	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR
BACLOFENE SUN 0,05 mg/ml, solution injectable	DE/H/1322/001	34009 576 805 9 6	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR
BACLOFENE SUN 10 mg/20 ml, solution pour perfusion	DE/H/1322/002	34009 576 808 8 6	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR
BACLOFENE SUN 10 mg/20 ml, solution pour perfusion	DE/H/1322/002	34009 576 807 1 8	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR
BACLOFENE SUN 10 mg/5 ml, solution pour perfusion	DE/H/1322/003	34009 576 809 4 7	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	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
BACLOFENE SUN 10 mg/5 ml, solution pour perfusion	DE/H/1322/003	34009 576 810 2 9	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR
Baklofen Sintetica 0,05 mg/ml raztopina za injiciranje	BE/H/0152/001	H/18/02474/001	SINTETICA GMBH	SI
Baklofen Sintetica 0,05 mg/ml raztopina za injiciranje	BE/H/0152/001	H/18/02474/002	SINTETICA GMBH	SI
Baklofen Sintetica 0,5 mg/ml raztopina za infundiranje	BE/H/0152/002	H/18/02474/003	SINTETICA GMBH	SI
Baklofen Sintetica 2 mg/ml raztopina za infundiranje	BE/H/0152/003	H/18/02474/004	SINTETICA GMBH	SI
Baklofen Sintetica 2 mg/ml raztopina za infundiranje	BE/H/0152/003	H/18/02474/005	SINTETICA GMBH	SI
Baklofen Sintetica 2 mg/ml raztopina za infundiranje	BE/H/0152/003	H/18/02474/006	SINTETICA GMBH	SI
Baklofen Sintetica 2 mg/ml raztopina za infundiranje	BE/H/0152/003	H/18/02474/007	SINTETICA GMBH	SI
Baklofen Sintetica Intratekalni 0,05 mg/ml otopina za injekciju	BE/H/0152/001	HR-H-242013306	SINTETICA GMBH	HR

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
Baklofen Sintetica Intratekalni 0,5 mg/ml otopina za infuziju	BE/H/0152/002	HR-H-358356156	SINTETICA GMBH	HR
Baklofen Sintetica Intratekalni 2 mg/ml otopina za infuziju	BE/H/0152/003	HR-H-140759373	SINTETICA GMBH	HR
Gablofen	DE/H/4034/001	53367	PIRAMAL CRITICAL CARE B.V.	DK
Gablofen	DE/H/4034/002	53368	PIRAMAL CRITICAL CARE B.V.	DK
Gablofen	DE/H/4034/003	53369	PIRAMAL CRITICAL CARE B.V.	DK
Gablofen	DE/H/4034/004	53370	PIRAMAL CRITICAL CARE B.V.	DK
Gablofen	DE/H/4034/006	53974	PIRAMAL CRITICAL CARE B.V.	DK
Gablofen	DE/H/4034/007	53975	PIRAMAL CRITICAL CARE B.V.	DK
Gablofen	DE/H/4034/008	53976	PIRAMAL CRITICAL CARE B.V.	DK

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
Gablofen 0,05 mg/ml injektions-/infusionsvätska, lösning i förfylld spruta	DE/H/4034/001	50387	PIRAMAL CRITICAL CARE B.V.	SE
Gablofen 0,05 mg/ml Injektionslösung/Infusionslösung in einer Fertigspritze	DE/H/4034/001	91009.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Gablofen 0,05 mg/ml oplossing voor injectie / infusie in een voorgevulde spuit	DE/H/4034/001	RVG 114568	PIRAMAL CRITICAL CARE B.V.	NL
Gablofen 0,5 mg/ml injektions-/infusionsvätska, lösning	DE/H/4034/006	50958	PIRAMAL CRITICAL CARE B.V.	SE
Gablofen 0,5 mg/ml injektions-/infusionsvätska, lösning i förfylld spruta	DE/H/4034/002	50388	PIRAMAL CRITICAL CARE B.V.	SE
Gablofen 0,5 mg/ml Injektionslösung/Infusionslösung	DE/H/4034/006	91966.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Gablofen 0,5 mg/ml Injektionslösung/Infusionslösung in einer Fertigspritze	DE/H/4034/002	91010.00.00	PIRAMAL CRITICAL CARE 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
Gablofen 0,5 mg/ml oplossing voor injectie / infusie	DE/H/4034/006	RVG 115222	PIRAMAL CRITICAL CARE B.V.	NL
Gablofen 0,5 mg/ml, oplossing voor injectie / infusie in voorgevulde spuit	DE/H/4034/002	RVG 114570	PIRAMAL CRITICAL CARE B.V.	NL
Gablofen 0.05 mg/ml solution for injection/infusion in pre-filled syringe	DE/H/4034/001	PL 37071/0008	PIRAMAL CRITICAL CARE LIMITED	XI
Gablofen 0.5 mg/ml solution for injection/infusion	DE/H/4034/006	PL 37071/0012	PIRAMAL CRITICAL CARE LIMITED	XI
Gablofen 0.5 mg/ml solution for injection/infusion in pre-filled syringe	DE/H/4034/002	PL 37071/009	PIRAMAL CRITICAL CARE LIMITED	XI
Gablofen 1 mg/ml injektions-/infusionsvätska, lösning	DE/H/4034/007	50959	PIRAMAL CRITICAL CARE B.V.	SE
Gablofen 1 mg/ml injektions-/infusionsvätska, lösning i förfylld spruta	DE/H/4034/003	50389	PIRAMAL CRITICAL CARE B.V.	SE
Gablofen 1 mg/ml Injektionslösung/Infusionslösung	DE/H/4034/007	91967.00.00	PIRAMAL CRITICAL CARE 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
Gablofen 1 mg/ml Injektionslösung/Infusionslösung in einer Fertigspritze	DE/H/4034/003	91011.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Gablofen 1 mg/ml oplossing voor injectie / infusie	DE/H/4034/007	RVG 115223	PIRAMAL CRITICAL CARE B.V.	NL
Gablofen 1 mg/ml oplossing voor injectie / infusie in een voorgevulde spuit	DE/H/4034/003	RVG 114571	PIRAMAL CRITICAL CARE B.V.	NL
Gablofen 1 mg/ml solution for injection/infusion	DE/H/4034/007	PL 37071/0013	PIRAMAL CRITICAL CARE LIMITED	XI
Gablofen 1 mg/ml solution for injection/infusion in pre-filled syringe	DE/H/4034/003	PL 37071/0010	PIRAMAL CRITICAL CARE LIMITED	XI
Gablofen 2 mg/ml injektions-/infusionsvätska, lösning	DE/H/4034/008	50960	PIRAMAL CRITICAL CARE B.V.	SE
Gablofen 2 mg/ml injektions-/infusionsvätska, lösning i förfylld spruta	DE/H/4034/004	50390	PIRAMAL CRITICAL CARE B.V.	SE
Gablofen 2 mg/ml Injektionslösung/Infusionslösung	DE/H/4034/008	91968.00.00	PIRAMAL CRITICAL CARE 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
Gablofen 2 mg/ml Injektionslösung/Infusionslösung in einer Fertigspritze	DE/H/4034/004	91012.00.00	PIRAMAL CRITICAL CARE B.V.	DE
Gablofen 2 mg/ml solution for injection/infusion	DE/H/4034/008	PL 37071/0014	PIRAMAL CRITICAL CARE LIMITED	XI
Gablofen 2 mg/ml solution for injection/infusion in pre-filled syringe	DE/H/4034/004	PL 37071/0011	PIRAMAL CRITICAL CARE LIMITED	XI
Gablofen 2 mg/ml, oplossing voor injectie / infusie	DE/H/4034/008	RVG 115224	PIRAMAL CRITICAL CARE B.V.	NL
Gablofen 2 mg/ml, oplossing voor injectie / infusie in voorgevulde spuit	DE/H/4034/004	RVG 114572	PIRAMAL CRITICAL CARE B.V.	NL
Lionova 0,5 mg/ml injeksjons-/infusjonsvæske, oppløsning	DK/H/2487/002	15-10617	ALTERNOVA A/S	NO
Lionova 0,5 mg/ml injektions-/infusionsvätska, lösning	DK/H/2487/002	52719	ALTERNOVA A/S	SE
Lionova 2 mg/ml injeksjons-/infusjonsvæske, oppløsning	DK/H/2487/003	15-10618	ALTERNOVA A/S	NO

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
Lionova 2 mg/ml injektions-/infusionsvätska, lösning	DK/H/2487/003	52720	ALTERNOVA A/S	SE
Lionova 50 mikrogram/ml injeksjons-/infusjonsvæske, oppløsning	DK/H/2487/001	15-10616	ALTERNOVA A/S	NO
Lionova 50 mikrogram/ml injektions-/infusionsvätska, lösning	DK/H/2487/001	52718	ALTERNOVA A/S	SE
Lionova, injektions-/infusionsvæske, opløsning	DK/H/2487/001	55626	ALTERNOVA A/S	DK
Lionova, injektions-/infusionsvæske, opløsning	DK/H/2487/002	55627	ALTERNOVA A/S	DK
Lionova, injektions-/infusionsvæske, opløsning	DK/H/2487/003	55628	ALTERNOVA A/S	DK
Lioresal 0,05 mg/1 ml soluzione iniettabile per uso intratecale	not available	022999054	NOVARTIS FARMA S.P.A.	IT
LIORESAL 0,05 mg/1 ml, solution injectable par voie intrathécale en ampoule	not available	3400955853763	NOVARTIS PHARMA S.A.S.	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
Lioresal 0,05 mg/ml solución inyectable	not available	62.346	NOVARTIS FARMACÉUTICA S.A.	ES
Lioresal 0,5 mg/ml injektions-/infusionsvätska, lösning	not available	12618	NOVARTIS SVERIGE AB	SE
Lioresal 0,5 mg/ml solución para perfusión	not available	62.347	NOVARTIS FARMACÉUTICA S.A.	ES
Lioresal 0,5 mg/ml stungulyf og innrennslislyf, lausn	not available	930165	NOVARTIS HEALTHCARE A/S	IS
Lioresal 10 mg/20 ml soluzione iniettabile per uso intratecale	not available	022999039	NOVARTIS FARMA S.P.A.	IT
LIORESAL 10 mg/20 ml, solution injectable pour perfusion par voie intrathécale en ampoule	not available	3400955853992	NOVARTIS PHARMA S.A.S.	FR
Lioresal 10 mg/5 ml soluzione iniettabile per uso intratecale	not available	022999041	NOVARTIS FARMA S.P.A.	IT
LIORESAL 10 mg/5 ml, solution injectable pour perfusion par voie intrathécale en ampoule	not available	3400955853824	NOVARTIS PHARMA S.A.S.	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
Lioresal 2 mg/ml injektions-/infusionsvätska, lösning	not available	12619	NOVARTIS SVERIGE AB	SE
Lioresal 2 mg/ml solución para perfusión	not available	62.348	NOVARTIS FARMACÉUTICA S.A.	ES
Lioresal 2 mg/ml stungulyf og innrennslislyf, lausn	not available	930166	NOVARTIS HEALTHCARE A/S	IS
Lioresal 50 mikrogram/ml injektions-/infusionsvätska, lösning	not available	12617	NOVARTIS SVERIGE AB	SE
Lioresal 50 mikrógrömm/ml stungulyf og innrennslislyf, lausn	not available	930164	NOVARTIS HEALTHCARE A/S	IS
Lioresal Intratecal 0,05 mg/1 ml Solução injetável	not available	2506681	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Lioresal Intratecal 10 mg/20 ml Solução injetável	not available	2506780	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Lioresal Intratecal 10 mg/5 ml Solução injetável	not available	2506889	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Lioresal Intrathecal 0,05 mg/1 ml Injektions- oder Infusionslösung	not available	BE174212	NOVARTIS PHARMA N.V.	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
Lioresal Intrathecal 0,05 mg/1 ml oplossing voor injectie of infusie	not available	BE174212	NOVARTIS PHARMA N.V.	BE
Lioresal Intrathecal 0,05 mg/1 ml roztwór do wstrzykiwań	DE/H/0522/001	12197	NOVARTIS POLAND SP. Z O. O.	PL
Lioresal Intrathecal 0,05 mg/1 ml solution injectable ou pour perfusion	not available	BE174212	NOVARTIS PHARMA N.V.	BE
Lioresal Intrathecal 10 mg/20 ml Injektions- oder Infusionslösung	not available	BE174194	NOVARTIS PHARMA N.V.	BE
Lioresal Intrathecal 10 mg/20 ml oplossing voor injectie of infusie	not available	BE174194	NOVARTIS PHARMA N.V.	BE
Lioresal Intrathecal 10 mg/20 ml roztwór do infuzji	DE/H/0522/003	12198	NOVARTIS POLAND SP. Z O. O.	PL
Lioresal Intrathecal 10 mg/20 ml solution injectable ou pour perfusion	not available	BE174194	NOVARTIS PHARMA N.V.	BE
Lioresal Intrathecal 10 mg/5 ml Injektions- oder Infusionslösung	not available	BE174203	NOVARTIS PHARMA N.V.	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
Lioresal Intrathecal 10 mg/5 ml oplossing voor injectie of infusie	not available	BE174203	NOVARTIS PHARMA N.V.	BE
Lioresal Intrathecal 10 mg/5 ml roztwór do infuzji	DE/H/0522/002	12199	NOVARTIS POLAND SP. Z O. O.	PL
Lioresal Intrathecal 10 mg/5 ml solution injectable ou pour perfusion	not available	BE174203	NOVARTIS PHARMA N.V.	BE
Lioresal, injektions- og infusionsvæske, opløsning	not available	15307	NOVARTIS HEALTHCARE A/S	DK
Lioresal, injektions- og infusionsvæske, opløsning	not available	15308	NOVARTIS HEALTHCARE A/S	DK
Lioresal, injektions- og infusionsvæske, opløsning	not available	15309	NOVARTIS HEALTHCARE A/S	DK
Lioresal® Intrathecal 0,05 mg/1 ml Injektionslösung	DE/H/0522/001	39917.00.00	NOVARTIS PHARMA GMBH	DE
Lioresal® Intrathecal 10 mg/20 ml Infusionslösung	DE/H/0522/003	39917.01.01	NOVARTIS PHARMA GMBH	DE
Lioresal® Intrathecal 10 mg/5 ml Infusionslösung	DE/H/0522/002	39917.00.01	NOVARTIS PHARMA GMBH	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
Lioresal® Intrathecal Infusion 10mg/20ml	not available	PL 00101/0501	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
Lioresal® Intrathecal Infusion 10mg/5ml	not available	PL 00101/0502	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
Lioresal® Intrathecal Injection 50micrograms/1ml	not available	PL 00101/0500	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
Lioresal® intrathekal 0,05 mg/1 ml - Ampullen	not available	1-21127	NOVARTIS PHARMA GMBH	AT
Lioresal® intrathekal 10 mg/20 ml - Ampulle	not available	1-21126	NOVARTIS PHARMA GMBH	AT
Lioresal® intrathekal 10 mg/5 ml - Ampulle	not available	1-21123	NOVARTIS PHARMA GMBH	AT
SPACYR 0,05 mg/1 ml Injektionslösung/Infusionslösung in einer Fertigspritze	DE/H/4034/001	BE489804	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 0,05 mg/1 ml oplossing voor injectie / infusie in voorgevulde spuit	DE/H/4034/001	BE489804	PIRAMAL CRITICAL CARE B.V.	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
SPACYR 0,05 mg/1 ml solution injectable/pour perfusion en seringue préremplie	DE/H/4034/001	BE489804	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 0,05 mg/ml solución inyectable y para perfusión en jeringa precargada	DE/H/4034/001	80229	PIRAMAL CRITICAL CARE B.V.	ES
SPACYR 0,05 mg/mL, solution injectable ou pour perfusion en seringue préremplie	DE/H/4034/001	34009 550 143 4 8	PIRAMAL CRITICAL CARE B.V.	FR
SPACYR 0,5 mg/ml solución inyectable y para perfusión EFG	DE/H/4034/006	80235	PIRAMAL CRITICAL CARE B.V.	ES
SPACYR 0,5 mg/ml solución inyectable y para perfusión en jeringa precargada	DE/H/4034/002	80230	PIRAMAL CRITICAL CARE B.V.	ES
SPACYR 0,5 mg/mL, solution injectable ou pour perfusion en seringue préremplie	DE/H/4034/002	34009 550 143 5 5	PIRAMAL CRITICAL CARE B.V.	FR
SPACYR 1 mg/ml solución inyectable y para perfusión	DE/H/4034/007	80233	PIRAMAL CRITICAL CARE B.V.	ES

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
SPACYR 1 mg/ml solución inyectable y para perfusión en jeringa precargada	DE/H/4034/003	80231	PIRAMAL CRITICAL CARE B.V.	ES
SPACYR 1 mg/mL, solution injectable ou pour perfusion	DE/H/4034/003	34009 550 143 8 6	PIRAMAL CRITICAL CARE B.V.	FR
SPACYR 1 mg/mL, solution injectable ou pour perfusion en seringue préremplie	DE/H/4034/003	34009 550 143 6 2	PIRAMAL CRITICAL CARE B.V.	FR
SPACYR 10 mg/20 ml Injektionslösung/Infusionslösung	DE/H/4034/006	BE489840	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 10 mg/20 ml Injektionslösung/Infusionslösung in einer Fertigspritze	DE/H/4034/002	BE489813	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 10 mg/20 ml oplossing voor injectie / infusie	DE/H/4034/006	BE489840	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 10 mg/20 ml oplossing voor injectie / infusie in voorgevulde spuit	DE/H/4034/002	BE489813	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 10 mg/20 ml solution injectable/pour perfusion	DE/H/4034/006	BE489840	PIRAMAL CRITICAL CARE B.V.	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
SPACYR 10 mg/20 ml solution injectable/pour perfusion en seringue préremplie	DE/H/4034/002	BE489813	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 2 mg/ml solución inyectable y para perfusión EFG	DE/H/4034/008	80234	PIRAMAL CRITICAL CARE B.V.	ES
SPACYR 2 mg/ml solución inyectable y para perfusión en jeringa precargada	DE/H/4034/004	80232	PIRAMAL CRITICAL CARE B.V.	ES
SPACYR 2 mg/mL, solution injectable ou pour perfusion en seringue préremplie	DE/H/4034/004	34009 550 143 7 9	PIRAMAL CRITICAL CARE B.V.	FR
SPACYR 20 mg/20 ml Injektionslösung/Infusionslösung	DE/H/4034/007	BE489857	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 20 mg/20 ml Injektionslösung/Infusionslösung in einer Fertigspritze	DE/H/4034/004	BE489822	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 20 mg/20 ml oplossing voor injectie / infusie	DE/H/4034/007	BE489857	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 20 mg/20 ml oplossing voor injectie / infusie in voorgevulde	DE/H/4034/004	BE489822	PIRAMAL CRITICAL CARE B.V.	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
spuit				
SPACYR 20 mg/20 ml solution injectable/pour perfusion	DE/H/4034/007	BE489857	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 20 mg/20 ml solution injectable/pour perfusion en seringue préremplie	DE/H/4034/004	BE489822	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 40 mg/20 ml Injektionslösung/Infusionslösung	DE/H/4034/008	BE489866	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 40 mg/20 ml Injektionslösung/Infusionslösung in einer Fertigspritze	DE/H/4034/004	BE489831	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 40 mg/20 ml oplossing voor injectie / infusie	DE/H/4034/008	BE489866	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 40 mg/20 ml oplossing voor injectie / infusie in voorgevulde spuit	DE/H/4034/004	BE489831	PIRAMAL CRITICAL CARE B.V.	BE
SPACYR 40 mg/20 ml solution injectable/pour perfusion	DE/H/4034/008	BE489866	PIRAMAL CRITICAL CARE B.V.	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
SPACYR 40 mg/20 ml solution injectable/pour perfusion en seringue préremplie	DE/H/4034/004	BE489831	PIRAMAL CRITICAL CARE B.V.	BE