



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2016
EMA/645247/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: baclofen

Procedure no.: PSUSA/00000293/201601

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525

Send a question via our website www.ema.europa.eu/contact

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 Aguettant	BE/H/0152/002	PL 14434/0027	Laboratoire Aguettant	United Kingdom
Baclofen Aguettant	BE/H/0152/003	PL 14434/0026	Laboratoire Aguettant	United Kingdom
Baclofen Aguettant	BE/H/152/01/DC	PL 14434/0024	Laboratoire Aguettant	United Kingdom
Baclofen Intrathecal Aguettant	BE/H/0152/001	BE384483	Laboratoire Aguettant	Belgium
Baclofen Intrathecal Aguettant	BE/H/0152/002 \$ BE/H/0152/003	BE384492 \$ BE384501 \$ BE384517	Laboratoire Aguettant	Belgium
Baclofen Intrathecal Meduna	BE/H/0152/001	78168.00.00	Sintetica Gmbh	Germany
Baclofen Intrathecal Meduna	BE/H/0152/002	78468.00.00	Sintetica Gmbh	Germany
Baclofen Intrathecal Meduna	BE/H/0152/003	78469.00.00	Sintetica Gmbh	Germany
Baclofen Intrathecal Meduna	BE/H/152/01-03/DC	1-29979	Sintetica Gmbh	Austria
Baclofen Meduna	BE/H/152/003	1-29981	Sintetica Gmbh	Austria
Baclofen Meduna	BE/H/152/01-03/DC	1-29980	Sintetica Gmbh	Austria
Baclofen Sun	DE/H/1322/001	70824.00.00	Sun Pharmaceuticals Germany Gmbh	Germany
Baclofen Sun	DE/H/1322/002 \$ DE/H/1322/003	70825.00.00 \$ 70826.00.00	Sun Pharmaceuticals Germany Gmbh	Germany
Baclofen Sun Pharmaceutical Industries Europe B.V.	DE/H/1322/001	PL 31750/0003	Sun Pharmaceutical Industries Europe B.V.	United Kingdom
Baclofen Sun Pharmaceutical Industries Europe B.V.	DE/H/1322/002 \$ DE/H/1322/003	PL 31750/0004 \$ PL 31750/0005	Sun Pharmaceutical Industries Europe B.V.	United Kingdom
Baclofene Aguettant		578 672-6 \$ 578 673-2 \$ 578 674-9	Laboratoire Aguettant	France
Baclofene Aguettant		578 675-5	Laboratoire Aguettant	France
Baclofene Bioindustria L.I.M.		041650019	Bioindustria Lim Laboratorio Italiano Medicinali Spa	Italy
Baclofene Bioindustria L.I.M.		041650021	Bioindustria Lim Laboratorio Italiano Medicinali Spa	Italy
Baclofene Bioindustria L.I.M.		041650033	Bioindustria Lim Laboratorio Italiano Medicinali Spa	Italy
Baclofene Molteni	BE/H/0152/001	040646010 \$ 040646059	L. Molteni And C. Dei F.Lli	Italy

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
			Alitti Società Di Esercizio S.P.A.	
Baclofene Molteni	BE/H/0152/002 \$ BE/H/0152/003	040646022/M \$ 040646034 \$ 040646046 \$ 040646061	L. Molteni And C. Dei F.Lli Alitti Società Di Esercizio S.P.A.	Italy
Baclofene Sun	DE/H/1322/001	039787015 \$ 039787027	Sun Pharmaceutical Industries Europe B.V.	Italy
Baclofene Sun	DE/H/1322/002 \$ DE/H/1322/003	039787039 \$ 039787041 \$ 039787054 \$ 039787066	Sun Pharmaceutical Industries Europe B.V.	Italy
Baclofeno Sun	DE/H/1322/001	72100	Sun Pharmaceutical Industries Europe B.V.	Spain
Baclofeno Sun	DE/H/1322/002 \$ DE/H/1322/003	72098 \$ 72099	Sun Pharmaceutical Industries Europe B.V.	Spain
Baclofène Sun	DE/H/1322/001	34009 576 805 9 6 \$ 34009 576 806 5 7	Sun Pharmaceutical Industries Europe B.V.	France
Baclofène Sun	DE/H/1322/002 \$ DE/H/1322/003	34009 576 807 1 8 \$ 34009 576 808 8 6 \$ 34009 576 809 4 7 \$ 34009 576 810 2 9	Sun Pharmaceutical Industries Europe B.V.	France
Gablofen	DE/H/4034/001/DC	53367	Mallinckrodt Pharmaceuticals Ireland Limited	Denmark
Gablofen	DE/H/4034/001/DC	PL 45463/0001	Mallinckrodt Pharmaceuticals Ireland Limited	United Kingdom
Gablofen	DE/H/4034/001/DC \$ DE/H/4034/002/DC \$ DE/H/4034/003/DC	80229 \$ 80230 \$ 80231	Mallinckrodt Spain S.L.U.	Spain
Gablofen	DE/H/4034/001/DC \$ DE/H/4034/002/DC \$ DE/H/4034/003/DC \$ DE/H/4034/004/DC	043328018 \$ 043328020 \$ 043328032 \$ 043328044	Mallinckrodt Pharmaceuticals Ireland Limited	Italy
Gablofen	DE/H/4034/001/DC \$ DE/H/4034/002/DC \$ DE/H/4034/003/DC \$ DE/H/4034/004/DC	91009.00.00 \$ 91010.00.00 \$ 91011.00.00 \$ 91012.00.00	Mallinckrodt Pharmaceuticals Ireland Limited	Germany
Gablofen	DE/H/4034/001/DC \$ DE/H/4034/002/DC \$	BE489804 \$ BE489813 \$ BE489822 \$ BE489831	Mallinckrodt Belgium Bvba	Belgium

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
	DE/H/4034/003/DC \$ DE/H/4034/004/DC			
Gablofen	DE/H/4034/001/DC \$ DE/H/4034/002/DC \$ DE/H/4034/003/DC \$ DE/H/4034/004/DC	RVG 114568 \$ RVG 114570 \$ RVG 114571 \$ RVG 114572	Mallinckrodt Pharmaceuticals Ireland Limited	Netherlands
Gablofen	DE/H/4034/001/DC \$ DE/H/4034/002/DC \$ DE/H/4034/004/DC	50387 \$ 50388 \$ 50390	Mallinckrodt Deutschland GmbH	Sweden
Gablofen	DE/H/4034/002/DC	53368	Mallinckrodt Pharmaceuticals Ireland Limited	Denmark
Gablofen	DE/H/4034/002/DC \$ DE/H/4034/003/DC	PL 45463/0002 \$ PL 45463/0003	Mallinckrodt Pharmaceuticals Ireland Limited	United Kingdom
Gablofen	DE/H/4034/003/DC \$ DE/H/4034/004	53369 \$ 53370	Mallinckrodt Pharmaceuticals Ireland Limited	Denmark
Gablofen	DE/H/4034/004/DC	80232	Mallinckrodt Spain S.L.U.	Spain
Gablofen	DE/H/4034/004/DC	91967.00.00	Mallinckrodt Pharmaceuticals Ireland Limited	Germany
Gablofen	DE/H/4034/004/DC	PL 45463/0004	Mallinckrodt Pharmaceuticals Ireland Limited	United Kingdom
Gablofen	DE/H/4034/006/DC	80235	Mallinckrodt Spain S.L.U.	Spain
Gablofen	DE/H/4034/006/DC	PL 45463/0005	Mallinckrodt Pharmaceuticals Ireland Limited	United Kingdom
Gablofen	DE/H/4034/006/DC \$ DE/H/4034/008/DC	043328069 \$ 043328083	Mallinckrodt Pharmaceuticals Ireland Limited	Italy
Gablofen	DE/H/4034/006/DC \$ DE/H/4034/008/DC	50958 \$ 50960	Mallinckrodt Deutschland GmbH	Sweden
Gablofen	DE/H/4034/006/DC \$ DE/H/4034/008/DC	53974 \$ 53976	Mallinckrodt Pharmaceuticals Ireland Limited	Denmark
Gablofen	DE/H/4034/006/DC \$ DE/H/4034/008/DC	91966.00.00 \$ 91968.00.00	Mallinckrodt Pharmaceuticals Ireland Limited	Germany
Gablofen	DE/H/4034/006/DC \$ DE/H/4034/008/DC	BE489840 \$ BE489866	Mallinckrodt Belgium Bvba	Belgium
Gablofen	DE/H/4034/006/DC \$	RVG 115222 \$ RVG 115224	Mallinckrodt Pharmaceuticals	NL

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
	DE/H/4034/008/DC		Ireland Limited	
Gablofen	DE/H/4034/007/DC	043328071	Mallinckrodt Pharmaceuticals Ireland Limited	IT
Gablofen	DE/H/4034/007/DC	50959	Mallinckrodt Deutschland Gmbh	SV
Gablofen	DE/H/4034/007/DC	80233	Mallinckrodt Spain S.L.U.	ES
Gablofen	DE/H/4034/007/DC	BE489857	Mallinckrodt Belgium Bvba	BE
Gablofen	DE/H/4034/007/DC	PL 45463/0006	Mallinckrodt Pharmaceuticals Ireland Limited	UK
Gablofen	DE/H/4034/007/DC	RVG 115223	Mallinckrodt Pharmaceuticals Ireland Limited	NL
Gablofen	DE/H/4034/008/DC	80234	Mallinckrodt Spain S.L.U.	ES
Gablofen	DE/H/4034/008/DC	PL 45463/0007	Mallinckrodt Pharmaceuticals Ireland Limited	UK
Lioresal		022999039 \$ 022999041 \$ 022999054	Novartis Farma S.P.A. (Art57)	IT
Lioresal		1-21123 \$ 1-21126	Novartis Pharma Gmbh (Art57)	AT
Lioresal		1-21127	Novartis Pharma Gmbh (Art57)	AT
Lioresal		12617 \$ 12618 \$ 12619-0	Novartis Sverige Ab (Art57)	SV
Lioresal		15307 \$ 15308 \$ 15309	Novartis Healthcare A/S (Art57)	DK
Lioresal		62.346	Novartis Farmacéutica S.A. (Art57)	ES
Lioresal		62.347	Novartis Farmacéutica S.A. (Art57)	ES
Lioresal		62.348	Novartis Farmacéutica S.A. (Art57)	ES
Lioresal		930164 \$ 930166	Novartis Healthcare A/S (Art57)	IS
Lioresal		930165	Novartis Healthcare A/S (Art57)	IS
Lioresal Intratecal		2506681	Novartis Farma - Produtos	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
			Farmacêuticos S.A. Art57	
Lioresal Intratecal		2506780	Novartis Farma - Produtos Farmacêuticos S.A. Art57	PT
Lioresal Intratecal		2506889	Novartis Farma - Produtos Farmacêuticos S.A. Art57	PT
Lioresal Intrathecaal		RVG 16815 \$ RVG 16816 \$ RVG 16817	Novartis Pharma B.V. (Art57)	NL
Lioresal Intrathecal		2011041144 \$ 2011041145 \$ 2011041146	Novartis Pharma N.V. (Art57)	LU
Lioresal Intrathecal		BE174194	Novartis Pharma N.V. (Art57)	BE
Lioresal Intrathecal		BE174203	Novartis Pharma N.V. (Art57)	BE
Lioresal Intrathecal		BE174212	Novartis Pharma N.V. (Art57)	BE
Lioresal Intrathecal		PL 00101/0500	Novartis Pharmaceuticals Uk Limited	UK
Lioresal Intrathecal		PL 00101/0501 \$ PL 00101/0502	Novartis Pharmaceuticals Uk Limited	UK
Lioresal Intrathecal	DE/H/0522/001	12197	Novartis Poland Sp. Z O. O. (Art57)	PL
Lioresal Intrathecal	DE/H/0522/001	39917.00.00	Novartis Pharma Gmbh (Art57)	DE
Lioresal Intrathecal	DE/H/0522/002	12199	Novartis Poland Sp. Z O. O. (Art57)	PL
Lioresal Intrathecal	DE/H/0522/002	39917.00.01	Novartis Pharma Gmbh (Art57)	DE
Lioresal Intrathecal	DE/H/0522/003	12198	Novartis Poland Sp. Z O. O. (Art57)	PL
Lioresal Intrathecal	DE/H/0522/003	39917.01.01	Novartis Pharma Gmbh (Art57)	DE
Liorésal		3400955853763	Novartis Pharma S.A.S. (Art57)	FR