



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 May 2024
EMA/320173/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): baclofen (oral use, for muscle spasticity indication)

Procedure No. PSUSA/00000294/202309



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 20 mg Tablets	not available	PL 12762/0612	MERCURY PHARMACEUTICALS LTD.	XI
Baclofen 5 mg Tablets	not available	PL 12762/0610	MERCURY PHARMACEUTICALS LTD.	XI
Baclofen 5 mg/5 ml Oral Solution	not available	PL 20416/0193	CRESCENT PHARMA LIMITED	XI
Lioresal 10 mg compresse	not available	022999015	NOVARTIS FARMA S.P.A.	IT
Lioresal 10 mg comprimate	not available	6380/2014/01	NOVARTIS PHARMA GMBH	RO
Lioresal 10 mg comprimate	not available	6380/2014/02	NOVARTIS PHARMA GMBH	RO
Lioresal 10 mg comprimés	not available	BE051021	NOVARTIS PHARMA N.V.	BE
Lioresal 10 mg comprimidos	not available	52.180	NOVARTIS FARMACÉUTICA S.A.	ES
Lioresal 10 mg comprimidos	not available	9319822	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Lioresal 10 mg comprimidos	not available	9319830	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Lioresal 10 mg tablete	not available	HR-H-786110495-01	NOVARTIS HRVATSKA D.O.O.	HR
Lioresal 10 mg Tablets	not available	PA 0896/017/001	NOVARTIS IRELAND LIMITED	IE
Lioresal 10 mg tablett	not available	6384	NOVARTIS FINLAND OY	FI
Lioresal 10 mg tabletta	not available	OGYI-T-842/01	NOVARTIS HUNGÁRIA KFT.	HU
Lioresal 10 mg Tabletten	not available	BE051021	NOVARTIS PHARMA N.V.	BE
Lioresal 10 mg tabletten	not available	BE051021	NOVARTIS PHARMA N.V.	BE
Lioresal 10 mg tabletter	not available	5725	NOVARTIS NORGE AS	NO
Lioresal 10 mg tabletti	not available	6384	NOVARTIS FINLAND OY	FI
LIORESAL 10 mg, comprimé sécable	not available	3400931716181	NOVARTIS PHARMA S.A.S.	FR
Lioresal 10, tabletten 10	not available	RVG 06347	NOVARTIS PHARMA B.V.	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
mg				
Lioresal 25 mg compresse	not available	022999027	NOVARTIS FARMA S.P.A.	IT
Lioresal 25 mg comprimate	not available	6381/2014/01	NOVARTIS PHARMA GMBH	RO
Lioresal 25 mg comprimés	not available	BE051012	NOVARTIS PHARMA N.V.	BE
Lioresal 25 mg comprimidos	not available	52.181	NOVARTIS FARMACÉUTICA S.A.	ES
Lioresal 25 mg comprimidos	not available	9319855	NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A.	PT
Lioresal 25 mg tablete	not available	HR-H-455944140-01	NOVARTIS HRVATSKA D.O.O.	HR
Lioresal 25 mg tablett	not available	6385	NOVARTIS FINLAND OY	FI
Lioresal 25 mg tablettá	not available	OGYI-T-842/02	NOVARTIS HUNGÁRIA KFT.	HU
Lioresal 25 mg Tabletten	not available	BE051012	NOVARTIS PHARMA N.V.	BE
Lioresal 25 mg tabletten	not available	BE051012	NOVARTIS PHARMA N.V.	BE
Lioresal 25 mg tabletter	not available	5726	NOVARTIS NORGE AS	NO
Lioresal 25 mg tabletti	not available	6385	NOVARTIS FINLAND OY	FI
Lioresal 5, tabletten 5 mg	not available	RVG 09086	NOVARTIS PHARMA B.V.	NL
Lioresal 5mg/5ml Oral Solution	not available	PA 0896/017/002	NOVARTIS IRELAND LIMITED	IE
Lioresal, oral opløsning	not available	13151	NOVARTIS HEALTHCARE A/S	DK
Lioresal, tabletter	not available	6074	NOVARTIS HEALTHCARE A/S	DK
Lioresal, tabletter	not available	10006	NOVARTIS HEALTHCARE A/S	DK
Lioresal® 10 mg - Tabletten	not available	14892	NOVARTIS PHARMA GMBH	AT
Lioresal® 10, 10 mg Tabletten	not available	6078226.01.00	NOVARTIS PHARMA GMBH	DE
Lioresal® 25 mg - Tabletten	not available	14893	NOVARTIS PHARMA GMBH	AT
Lioresal® 25, 25 mg Tabletten	not available	6078226.02.00	NOVARTIS PHARMA GMBH	DE
Lioresal® 5, 5 mg Tabletten	not available	6078226.00.00	NOVARTIS PHARMA GMBH	DE
Lioresal® Liquid	not available	PL 00101/0503	NOVARTIS	XI

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			PHARMACEUTICALS UK LIMITED	
Lioresal® Tablets 10mg	not available	PL 00101/0504	NOVARTIS PHARMACEUTICALS UK LIMITED	XI