



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 June 2017
EMA/PRAC/343350/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): baclofen (oral)

Procedure No.: PSUSA/00000294/201609



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 10 mg Tabletten	not available	BE051021	NOVARTIS PHARMA N.V.	BE
Lioresal 25 mg Tabletten	not available	BE051012	NOVARTIS PHARMA N.V.	BE
LIORESAL 25 MG COMPRIMATE	not available	6381/2014/01	NOVARTIS PHARMA GMBH	RO
LIORESAL 10 MG COMPRIMATE	not available	6380/2014/01	NOVARTIS PHARMA GMBH	RO
Lioresal 10 mg tablete	not available	UP/I-530-09/11-02/617	NOVARTIS HRVATSKA D.O.O.	HR
Lioresal 25 mg tablete	not available	UP/I-530-09/11-02/618	NOVARTIS HRVATSKA D.O.O.	HR
Lioresal 10 mg Tabletten	not available	0010/93/05/2445	NOVARTIS PHARMA N.V.	LU
Lioresal 25 mg Tabletten	not available	0010/93/05/2446	NOVARTIS PHARMA N.V.	LU
Lioresal® Liquid	not available	PL 00101/0503	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
LIORESAL 10 mg compresse	not available	022999015	NOVARTIS FARMA S.P.A.	IT
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 25 mg compresse	not available	022999027	NOVARTIS FARMA S.P.A.	IT
Lioresal 25 mg comprimidos	not available	9319855	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
LIORESAL 10 mg comprimidos	not available	52180	NOVARTIS FARMACÉUTICA S.A.	ES
Lioresal 10 mg tabletter	not available	6384	NOVARTIS FINLAND OY	FI
Lioresal 10 mg tabletti	not available	6384	NOVARTIS FINLAND OY	FI
LIORESAL 25 mg comprimidos	not available	52.181	NOVARTIS FARMACÉUTICA S.A.	ES
Lioresal 25 mg tabletter	not available	6385	NOVARTIS FINLAND OY	FI
Lioresal 25 mg tabletti	not available	6385	NOVARTIS FINLAND OY	FI
Lioresal	not available	06074	NOVARTIS HEALTHCARE A/S	DK
Lioresal	not available	10006	NOVARTIS HEALTHCARE A/S	DK
Lioresal	not available	13151	NOVARTIS HEALTHCARE A/S	DK
LIORESAL® 10, 10 MG TABLETTE	not available	6078226.01.00	NOVARTIS PHARMA GMBH	DE
Lioresal 10 mg tableta	not available	OGYI-T-842/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Lioresal 10, tabletten 10 mg	not available	RVG 06347	NOVARTIS PHARMA B.V.	NL
Lioresal® 25, 25 mg Tabletten	not available	6078226.02.00	NOVARTIS PHARMA GMBH	DE
Lioresal 25 mg tableta	not available	OGYI-T-842/02	NOVARTIS HUNGÁRIA KFT. PHARMA	HU

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 25, tabletten 25 mg	not available	RVG 06348	NOVARTIS PHARMA B.V.	NL
Lioresal® 5, 5 mg Tabletten	not available	6078226.00.00	NOVARTIS PHARMA GMBH	DE
Lioresal 5, tabletten 5 mg	not available	RVG 09086	NOVARTIS PHARMA B.V.	NL
Lioresal® Tablets 10mg	not available	PL 00101/0504	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Lioresal 10 mg - Tabletten	not available	14892	NOVARTIS PHARMA GMBH	AT
Lioresal 10 mg comprimés	not available	BE051021	NOVARTIS PHARMA N.V.	BE
LIORESAL 10 MG COMPRIMÉS	not available	0010/93/05/2445	NOVARTIS PHARMA N.V.	LU
Lioresal 10 mg tabletten	not available	BE051021	NOVARTIS PHARMA N.V.	BE
Lioresal 10 mg tabletter	not available	8869	NOVARTIS SVERIGE AB	SE
LIORESAL 10 mg, comprimé sécable	not available	3400931716181	NOVARTIS PHARMA S.A.S.	FR
Lioresal 25 mg - Tabletten	not available	14893	NOVARTIS PHARMA GMBH	AT
Lioresal 25 mg comprimés	not available	BE051012	NOVARTIS PHARMA N.V.	BE
Lioresal 25 mg comprimés	not available	0010/93/05/2446	NOVARTIS PHARMA N.V.	LU
Lioresal 25 mg tabletten	not available	BE051012	NOVARTIS PHARMA N.V.	BE
Lioresal 25 mg tabletter	not available	08870-0	NOVARTIS SVERIGE AB	SE
LIORESAL 10 MG TABLETS	not available	PA 13/58/1	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Lioresal 5mg/5ml Oral Solution	not available	PA 13/58/2	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
Lioresal 25 mg töflur	not available	772127	NOVARTIS HEALTHCARE A/S	IS
Lioresal 10 mg tabletter	not available	5725	NOVARTIS NORGE AS	NO
Lioresal 25 mg tabletter	not available	5726	NOVARTIS NORGE AS	NO
BACLOFEN-POLPHARMA 10 mg tablety	not available	63/102/81-A/C	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	CZ
Baclofen 5mg/5ml Oral Solution	not available	PL 20416/0193	CRESCENT PHARMA LIMITED	UK