



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/CMDh/422905/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: baclofen (oral)

Procedure no.: PSUSA/00000294/202009

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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
BACLOCUR 10 mg, comprimé pelliculé sécable	not available	34009 301 635 2 8	ETHYPHARM	FR
BACLOCUR 10 mg, comprimé pelliculé sécable	not available	34009 301 635 3 5	ETHYPHARM	FR
BACLOCUR 10 mg, comprimé pelliculé sécable	not available	34009 301 635 4 2	ETHYPHARM	FR
BACLOCUR 10 mg, comprimé pelliculé sécable	not available	34009 301 635 6 6	ETHYPHARM	FR
BACLOCUR 10 mg, comprimé pelliculé sécable	not available	34009 301 635 7 3	ETHYPHARM	FR
BACLOCUR 10 mg, comprimé pelliculé sécable	not available	34009 301 635 8 0	ETHYPHARM	FR
BACLOCUR 20 mg, comprimé pelliculé sécable	not available	34009 301 635 9 7	ETHYPHARM	FR
BACLOCUR 20 mg, comprimé pelliculé sécable	not available	34009 301 636 0 3	ETHYPHARM	FR
BACLOCUR 20 mg, comprimé pelliculé sécable	not available	34009 301 636 2 7	ETHYPHARM	FR
BACLOCUR 20 mg, comprimé pelliculé sécable	not available	34009 301 636 3 4	ETHYPHARM	FR
BACLOCUR 20 mg, comprimé pelliculé sécable	not available	34009 301 636 4 1	ETHYPHARM	FR
BACLOCUR 20 mg,	not available	34009 301 636 5 8	ETHYPHARM	FR

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comprimé pelliculé sécable				
BACLOCUR 30 mg, comprimé pelliculé sécable	not available	34009 301 868 8 6	ETHYPHARM	FR
BACLOCUR 30 mg, comprimé pelliculé sécable	not available	34009 301 869 2 3	ETHYPHARM	FR
BACLOCUR 30 mg, comprimé pelliculé sécable	not available	34009 301 869 0 9	ETHYPHARM	FR
BACLOCUR 30 mg, comprimé pelliculé sécable	not available	34009 301 869 1 6	ETHYPHARM	FR
BACLOCUR 30 mg, comprimé pelliculé sécable	not available	34009 301 868 9 3	ETHYPHARM	FR
BACLOCUR 30 mg, comprimé pelliculé sécable	not available	34009 301 869 3 0	ETHYPHARM	FR
BACLOCUR 40 mg, comprimé pelliculé sécable	not available	34009 301 636 6 5	ETHYPHARM	FR
BACLOCUR 40 mg, comprimé pelliculé sécable	not available	34009 301 636 7 2	ETHYPHARM	FR
BACLOCUR 40 mg, comprimé pelliculé sécable	not available	34009 301 636 8 9	ETHYPHARM	FR
BACLOCUR 40 mg, comprimé pelliculé sécable	not available	34009 301 636 9 6	ETHYPHARM	FR
BACLOCUR 40 mg, comprimé pelliculé	not available	34009 301 637 0 2	ETHYPHARM	FR

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sécable				
BACLOCUR 40 mg, comprimé pelliculé sécable	not available	34009 301 637 1 9	ETHYPHARM	FR
Baclofen 20 mg Tablets	not available	PL 12762/0612	MERCURY PHARMACEUTICALS LTD.	XI
Baclofen 25mg Tablets	not available	PL 44041/0127	NOUMED LIFE SCIENCES	UK
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
BACLOFEN-POLPHARMA 10 mg tablety	not available	63/102/81-A/C	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	CZ
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

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Lioresal 10 mg tableta	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 tablettér	not available	6384	NOVARTIS FINLAND OY	FI
Lioresal 10 mg tablettér	not available	5725	NOVARTIS NORGE AS	NO
Lioresal 10 mg tablettér	not available	8869	NOVARTIS SVERIGE AB	SE
Lioresal 10 mg tabletti	not available	6384	NOVARTIS FINLAND OY	FI
LIORÉVAL 10 mg, comprimé sécable	not available	3400931716181	NOVARTIS PHARMA S.A.S.	FR
Lioresal 10, tabletten 10 mg	not available	RVG 06347	NOVARTIS PHARMA B.V.	NL
LIORESAL 25 mg compresse	not available	022999027	NOVARTIS FARMA S.P.A.	IT
Lioresal 25 mg comprimata	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 FARMACÊUTICOS S.A.	PT
Lioresal 25 mg tablete	not available	HR-H-455944140-01	NOVARTIS HRVATSKA D.O.O.	HR
Lioresal 25 mg tableta	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 tablettér	not available	6385	NOVARTIS FINLAND OY	FI
Lioresal 25 mg tablettér	not available	5726	NOVARTIS NORGE AS	NO
Lioresal 25 mg tablettér	not available	8870	NOVARTIS SVERIGE AB	SE
Lioresal 25 mg tabletti	not available	6385	NOVARTIS FINLAND OY	FI
Lioresal 25 mg töflur	not available	772127	NOVARTIS HEALTHCARE A/S	IS
Lioresal 25, tabletten 25	not available	RVG 06348	NOVARTIS PHARMA B.V.	NL

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mg				
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	06074	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 PHARMACEUTICALS UK LIMITED	XI
Lioresal® Tablets 10mg	not available	PL 00101/0504	NOVARTIS PHARMACEUTICALS UK LIMITED	XI