



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam, 12 January 2023
EMA/60182/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): betaxolol

Procedure No.: PSUSA/00000401/202205



Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
BETOPTIC 0,5 POUR CENT, collyre	not available	3400932904587	NOVARTIS PHARMA S.A.S.	FR
BETOPTIC 0,5% w/v, οφθαλμικές σταγόνες, διάλυμα	not available	193150101	NOVARTIS (HELLAS) S.A.C.I.	GR
BETOPTIC 0.25% w/v Eye Drops, Suspension	not available	PL 00101/0990	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
Betoptic 0.5% w/v eye drops, solution	not available	PL 00101/0991	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
Betoptic 2,5 mg/ml szuszpenziós szemcsepp	not available	OGYI-T-5293/01	NOVARTIS HUNGÁRIA KFT.	HU
Betoptic 5 mg/ml acu pilieni, šķīdums	not available	99-1056	IMMEDICA PHARMA AB	LV
BETOPTIC 5 mg/ml Augentropfen, Lösung	not available	BE133077	NOVARTIS PHARMA N.V.	BE
Betoptic 5 mg/ml Colírio, solução	not available	8753707	IMMEDICA PHARMA AB	PT
BETOPTIC 5 mg/ml collirio, soluzione	not available	025899016	IMMEDICA PHARMA AB	IT
BETOPTIC 5 mg/ml kapi za oko, otopina	not available	HR-H-709311743	IMMEDICA PHARMA AB	HR
BETOPTIC 5 mg/ml kapljice za oko, raztopina	not available	H/93/00272/002	IMMEDICA PHARMA AB	SI
BETOPTIC 5 mg/ml ocná roztoková instilácia	not available	64/0203/88-C/S	IMMEDICA PHARMA AB	SK
Betoptic 5 mg/ml ögondroppar, lösning	not available	9518	IMMEDICA PHARMA AB	FI
Betoptic 5 mg/ml ögondroppar, lösning	not available	10388	NOVARTIS SVERIGE AB	SE
Betoptic 5 mg/ml oldatos szemcsepp	not available	OGYI-T-1727/01	IMMEDICA PHARMA AB	HU
BETOPTIC 5 mg/ml oogdruppels, oplossing.	not available	BE133077	NOVARTIS PHARMA N.V.	BE
Betoptic 5 mg/ml øyedråper, oppløsning	not available	7399	NOVARTIS NORGE AS	NO
Betoptic 5 mg/ml silmätipat, liuos	not available	9518	IMMEDICA PHARMA AB	FI
BETOPTIC 5 mg/ml, collyre en solution	not available	BE133077	NOVARTIS PHARMA N.V.	BE
BETOPTIC ocní kapky, roztok	not available	64/203/88-C	NOVARTIS S.R.O.,	CZ
BETOPTIC S 0,25% w/v, οφθαλμικές σταγόνες, εναιώρημα	not available	193150201	NOVARTIS (HELLAS) S.A.C.I.	GR

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Betoptic S 2,5 mg/ml akių lašai (suspensija)	not available	LT/1/92/0089/001	SIA NOVARTIS BALTICS	LT
BETOPTIC S 2,5 mg/ml kapljice za oko, suspensija	not available	H/93/00272/001	IMMEDICA PHARMA AB	SI
BETOPTIC S 2,5 mg/ml očné suspenzné kvapky	not available	64/0600/97-S	IMMEDICA PHARMA AB	SK
Betoptic S 2,5 mg/ml oční kapky, suspenze	not available	64/1131/94-C	NOVARTIS S.R.O.,	CZ
Betoptic S 2,5 mg/ml ögondroppar, suspension	not available	11503	NOVARTIS SVERIGE AB	SE
Betoptic S 2,5 mg/ml ögondroppar, suspension, endosbehållare	not available	12604	NOVARTIS SVERIGE AB	SE
Betoptic S 2,5 mg/ml øyedråper, suspensjon	not available	7924	NOVARTIS NORGE AS	NO
BETOPTIC S 2,5 mg/ml picături oftalmice, suspensie	not available	13500/2020/01	NOVARTIS PHARMA GMBH	RO
Betoptic S 2,5 mg/ml silmatilgad, suspensioon	not available	234398	IMMEDICA PHARMA AB	EE
Betoptic S 2,5 mg/ml ögondroppar, suspension	not available	11099	IMMEDICA PHARMA AB	FI
Betoptic S 2,5 mg/ml ögondroppar, suspension i endosbehållare	not available	12085	IMMEDICA PHARMA AB	FI
Betoptic S 2,5 mg/ml silmätipat, suspensio	not available	11099	IMMEDICA PHARMA AB	FI
Betoptic S 2,5 mg/ml silmätipat, suspensio, kerta-annospakkaus	not available	12085	IMMEDICA PHARMA AB	FI
BETOPTIC S Augensuspension	not available	1-20898	IMMEDICA PHARMA AB	AT
BETOPTIC S SINGLE DOSE, oogdruppels 2,5 mg/ml	not available	RVG 17110	IMMEDICA PHARMA AB	NL
BETOPTIC S, 2,5 mg/ml krople do oczu, zawiesina	not available	R/1865	IMMEDICA PHARMA AB	PL
BETOPTIC S, 2.5 mg/ml, eye drops, suspension	not available	MA 1249/00801	NOVARTIS IRELAND LIMITED	MT
Betoptic S, øjendråber, suspension	not available	14779	IMMEDICA PHARMA AB	DK
BETOPTIC S, oogdruppels (suspensie) 2,5 mg/ml	not available	RVG 15337	IMMEDICA PHARMA AB	NL

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
BETOPTIC Suspension (= BETOPTIC S.) 2,5 mg/ml Augentropfensuspension	not available	BE160334	NOVARTIS PHARMA N.V.	BE
BETOPTIC Suspension (= BETOPTIC S.) 2,5 mg/ml oogdruppels, suspensie.	not available	BE160334	NOVARTIS PHARMA N.V.	BE
BETOPTIC Suspension (= BETOPTIC S.) 2,5 mg/ml, collyre en suspension	not available	BE160334	NOVARTIS PHARMA N.V.	BE
BETOPTIC Suspension (= BETOPTIC S.) SINGLE DOSE 2,5 mg/ml Augentropfensuspension	not available	BE169784	NOVARTIS PHARMA N.V.	BE
BETOPTIC Suspension (= BETOPTIC S.) SINGLE DOSE 2,5 mg/ml oogdruppels, suspensie	not available	BE169784	NOVARTIS PHARMA N.V.	BE
BETOPTIC Suspension (= BETOPTIC S.) SINGLE DOSE 2,5 mg/ml, collyre en suspension	not available	BE169784	NOVARTIS PHARMA N.V.	BE
BETOPTIC SUSPENSION 2,5 mg/ml colirio en suspensi3n	not available	61.015	IMMEDICA PHARMA AB	ES
BETOPTIC SUSPENSION SINGLE DOSE 0.25% w/v, Eye Drops	not available	PL 00101/0992	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
Betoptic 0,5%, 5 mg/ml, krople do oczu, roztw3r	not available	R/1866	IMMEDICA PHARMA AB	PL
BETOPTIMA® 5 mg/ml Augentropfen	not available	5437.00.00	IMMEDICA PHARMA AB	DE
KERLON 20 mg compresse rivestite con film	not available	025317013	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
KERLONE 20 mg, comprim3 pellicul3 s3cable	not available	34009 325 494 2 9	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KERLONE 20 mg, comprim3 pellicul3 s3cable	not available	34009 371 464 5 6	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
KERLONE 20 mg, comprim3 pellicul3 s3cable	not available	34009 371 465 1 7	CHEPLAPHARM ARZNEIMITTEL GMBH	FR

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Kerlone 20 mg Filmtabletten	not available	2980.00.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
KERLONE®	not available	8536/6-2-2007	LAVIPHARM HELLAS AE	GR
Lokren 10 mg plévele dengtos tabletés	not available	LT/1/97/2151/001	CHEPLAPHARM ARZNEIMITTEL GMBH	LT
Lokren 20 mg comprimate filmate	not available	7016/2014/01	CHEPLAPHARM ARZNEIMITTEL GMBH	RO
Lokren 20 mg comprimate filmate	not available	7016/2014/03	CHEPLAPHARM ARZNEIMITTEL GMBH	RO
Lokren 20 mg comprimate filmate	not available	7016/2014/02	CHEPLAPHARM ARZNEIMITTEL GMBH	RO
Lokren 20 mg filmtabletta	not available	OGYI-T-2169/01	CHEPLAPHARM ARZNEIMITTEL GMBH	HU
Lokren 20 mg plévele dengtos tabletés	not available	LT/1/97/2151/002	CHEPLAPHARM ARZNEIMITTEL GMBH	LT
Lokren 20 mg potahované tablety	not available	58/297/91-C	CHEPLAPHARM ARZNEIMITTEL GMBH	CZ
Lokren 20 mg filmom obalené tablety	not available	58/0297/91-CS	CHEPLAPHARM ARZNEIMITTEL GMBH	SK
LOKREN 20, 20 mg, tabletki powlekane	not available	R/0374	CHEPLAPHARM ARZNEIMITTEL GMBH	PL
БЕТОПТИК S 0,25% капки за очи, суспензия	not available	20000307	NOVARTIS PHARMA GMBH	BG