



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 June 2017
EMA/366180/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): brimonidine (except for the centrally authorised product)

Procedure No.: PSUSA/00000430/201609



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
ALFADINA 2mg/ml, colirio en solución	DK/H/1268/001	71358	BAUSCH & LOMB, S.A.	ES
Alphagan	UK/H/0199/001	18999	ALLERGAN PHARMACEUTICALS IRELAND	DK
Alphagan 0,2 % (2 mg/ml) øyedråper, oppløsning	UK/H/0199/001	02-1012	ALLERGAN PHARMACEUTICALS IRELAND	NO
Alphagan 0,2 % (2 mg/ml) silmätipat, liuos	UK/H/0199/001	12955	ALLERGAN PHARMACEUTICALS IRELAND	FI
Alphagan 0,2 % Augentropfen	UK/H/0199/001	1-22311	ALLERGAN PHARMACEUTICALS IRELAND	AT
Alphagan 0,2 % m/v (2 mg/ml) Augentropfen	UK/H/0199/001	41359.00.00	ALLERGAN PHARMACEUTICALS IRELAND	DE
Alphagan 0,2 % m/v (2 mg/ml), collyre en solution	UK/H/0199/001	BE240055	ALLERGAN PHARMACEUTICALS IRELAND	BE
Alphagan 0,2 % m/v (2 mg/ml), collyre en solution	UK/H/0199/001	BE191152	ALLERGAN PHARMACEUTICALS IRELAND	BE
Alphagan 0,2 % m/v (2 mg/ml), collyre en solution	UK/H/0199/001	1279/02/10/6817	ALLERGAN PHARMACEUTICALS IRELAND	LU
Alphagan 0,2% (2 mg/ml) augndropar, lausn	UK/H/0199/001	IS/1/02/021/01	ALLERGAN PHARMACEUTICALS IRELAND	IS
Alphagan 0,2% (2 mg/ml) ögondroppar, lösning	UK/H/0199/001	12955	ALLERGAN PHARMACEUTICALS IRELAND	FI
Alphagan 0,2% (2 mg/ml) ögondroppar, lösning	UK/H/0199/001	13744	ALLERGAN PHARMACEUTICALS IRELAND	SE
Alphagan 0,2% p/v (2 mg/ml) collirio, soluzione	UK/H/0199/001	033490018	ALLERGAN PHARMACEUTICALS IRELAND	IT

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
Alphagan 0,2% p/v (2 mg/ml) collirio, soluzione	UK/H/0199/001	033490020	ALLERGAN PHARMACEUTICALS IRELAND	IT
Alphagan 0,2% p/v (2 mg/ml) collirio, soluzione	UK/H/0199/001	033490032	ALLERGAN PHARMACEUTICALS IRELAND	IT
Alphagan 0,2% w/v (2 mg/ml) oogdruppels, oplossing	UK/H/0199/001	BE191152	ALLERGAN PHARMACEUTICALS IRELAND	BE
Alphagan 0,2% w/v (2 mg/ml) oogdruppels, oplossing	UK/H/0199/001	BE240055	ALLERGAN PHARMACEUTICALS IRELAND	BE
Alphagan 0,2% w/v (2 mg/ml) oogdruppels, oplossing	UK/H/0199/001	RVG 21754	ALLERGAN PHARMACEUTICALS IRELAND	NL
Alphagan 0.2% w/v (2 mg/ml) eye drops, solution	UK/H/0199/001	PA 148/6/1	ALLERGAN PHARMACEUTICALS IRELAND	IE
Alphagan 0.2% w/v (2 mg/ml) eye drops, solution	not available	AA626/00101	ALLERGAN PHARMACEUTICALS IRELAND	MT
Alphagan 0.2% w/v (2 mg/ml) οφθαλμικές σταγόνες, διάλυμα	UK/H/0199/001	42442/19-6-2015	ALLERGAN PHARMACEUTICALS IRELAND	GR
ALPHAGAN 2 mg/ml kapi za oko, otopina	not available	HR-H-063917030	ALLERGAN PHARMACEUTICALS IRELAND	HR
Alphagan Oční kapky, roztok	not available	64/327/00-C	ALLERGAN PHARMACEUTICALS IRELAND	CZ
Alphagan, 2 mg/ml, krople do oczu, roztwór	not available	8650	ALLERGAN PHARMACEUTICALS IRELAND	PL
ALPHAGAN® 0,2 % m/V (2 mg/ml) Augentropfen, Lösung	UK/H/0199/001	BE240055	ALLERGAN PHARMACEUTICALS IRELAND	BE

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
ALPHAGAN® 0,2 % m/V (2 mg/ml) Augentropfen, Lösung	UK/H/0199/001	BE191152	ALLERGAN PHARMACEUTICALS IRELAND	BE
Alphastad, øjendråber, opløsning	DK/H/1272/001	41492	STADA ARZNEIMITTEL AG	DK
Biprolast, 2 mg/ml, krople do oczu, roztwór	DK/H/1964/001	18446	ADAMED	PL
Briglau 2 mg/ml acu pilieni, šķīdums	NL/H/2433/001	12-0317	MEDANA PHARMA SPOLKA AKCYJNA	LV
Briglau 2 mg/ml akių lašai (tirpalas)	NL/H/2433/001	LT/1/12/3153/001	MEDANA PHARMA SPOLKA AKCYJNA	LT
Briglau 2 mg/ml, oogdruppels, oplossing	NL/H/2433/001	RVG 110407	MEDANA PHARMA SPOLKA AKCYJNA	NL
Briglau PPH, 2 mg/ml, krople do oczu, roztwór	AT/H/0476/001	20094	ZAKŁADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Briglau, 2 mg/ml, krople do oczu, roztwór	NL/H/2433/001	20910	MEDANA PHARMA SPOLKA AKCYJNA	PL
Brimo Ophtal® 2mg/ml, Augentropfen; Lösung	DK/H/1268/001	69936.00.00	DR. WINZER PHARMA GMBH	DE
BRIMOFTAL 2ml/mg collirio, soluzione	DK/H/1384/001	038714010	BRUSCHETTINI S.R.L	IT
BRIMOFTAL 2ml/mg collirio, soluzione	DK/H/1384/001	038714022	BRUSCHETTINI S.R.L	IT
BRIMOFTAL 2ml/mg collirio, soluzione	DK/H/1384/001	038714034	BRUSCHETTINI S.R.L	IT
BRIMOFTAL 2ml/mg collirio, soluzione	DK/H/1384/001	038714046	BRUSCHETTINI S.R.L	IT
BRIMOFTAL 2ml/mg collirio, soluzione	DK/H/1384/001	038714059	BRUSCHETTINI S.R.L	IT
Brimoftal, øjendråber, opløsning	DK/H/1384/001	42075	BRUSCHETTINI S.R.L	DK
Brimogen 2 mg/ml Augentropfen, Lösung	AT/H/0476/001	1-30106	EYEPHARM GMBH & CO. KG	AT
BRIMOGEN 2 mg/ml Augentropfen, Lösung	AT/H/0476/001	76671.00.00	EYEPHARM GMBH & CO. KG	DE
Brimonidin Arcana 2 mg/ml - Augentropfen	DK/H/1264/001	1-28055	ARCANA ARZNEIMITTEL GMBH	AT

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
Brimonidin Hexal 2 mg/ml ögonddroppar, lösning	DK/H/1267/001	28100	HEXAL A/S	SE
Brimonidin Medops 2 mg/ml kapljice za oko, raztopina	AT/H/0476/001	H/12/00308/001-003	EYEPHARM GMBH & CO. KG	SI
Brimonidina Bausch & Lomb 2 mg/ml collirio, soluzione	DK/H/1268/001	039652019	BAUSCH & LOMB IOM S.P.A	IT
Brimonidina Bausch & Lomb 2 mg/ml collirio, soluzione	DK/H/1268/001	039652021	BAUSCH & LOMB IOM S.P.A	IT
Brimonidina Bausch & Lomb 2 mg/ml collirio, soluzione	DK/H/1268/001	039652033	BAUSCH & LOMB IOM S.P.A	IT
Brimonidina Bausch & Lomb 2 mg/ml collirio, soluzione	DK/H/1268/001	039652058	BAUSCH & LOMB IOM S.P.A	IT
Brimonidina Bausch & Lomb 2 mg/ml collirio, soluzione	DK/H/1268/001	039652045	BAUSCH & LOMB IOM S.P.A	IT
BRIMONIDINA CINFA 2 MG/ML COLIRIO EN SOLUCION	IT/H/0147/001/DC	71405	LABORATORIOS CINFA, S.A.	ES
BRIMONIDINA EG 2 mg/ml collirio, soluzione	DK/H/1272/001	038644050	EG SPA	IT
BRIMONIDINA EG 2 mg/ml collirio, soluzione	DK/H/1272/001	038644047	EG SPA	IT
BRIMONIDINA EG 2 mg/ml collirio, soluzione	DK/H/1272/001	038644023	EG SPA	IT
BRIMONIDINA EG 2 mg/ml collirio, soluzione	DK/H/1272/001	038644035	EG SPA	IT
BRIMONIDINA EG 2 mg/ml collirio, soluzione	DK/H/1272/001	038644011	EG SPA	IT
Brimonidina Kern Pharma 2 mg/ml colirio en solución	not available	77.144	KERN PHARMA, S.L.	ES
Brimonidina Mylan 2 mg/ml colirio en solución	DK/H/1264/001	70934	MYLAN PHARMACEUTICALS S.L.	ES
Brimonidina Mylan 2 mg/ml colírio, solução	DK/H/1264/001	5137625	MYLAN, LDA	PT
Brimonidina Mylan 2 mg/ml colírio, solução	DK/H/1264/001	5137617	MYLAN, LDA	PT
Brimonidina Mylan Generics 2 mg/ml collirio, soluzione	DK/H/1264/001	038634010	MYLAN S.P.A.	IT

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
Brimonidina Mylan Generics 2 mg/ml collirio, soluzione	DK/H/1264/001	038634022	MYLAN S.P.A.	IT
Brimonidina Mylan Generics 2 mg/ml collirio, soluzione	DK/H/1264/001	038634034	MYLAN S.P.A.	IT
Brimonidina Mylan Generics 2 mg/ml collirio, soluzione	DK/H/1264/001	038634046	MYLAN S.P.A.	IT
Brimonidina Mylan Generics 2 mg/ml collirio, soluzione	DK/H/1264/001	038634059	MYLAN S.P.A.	IT
Brimonidina ratiopharm 2 mg/ml collirio, soluzione	DK/H/1270/001	038671044	RATIOPHARM GMBH	IT
Brimonidina ratiopharm 2 mg/ml collirio, soluzione	DK/H/1270/001	038671057	RATIOPHARM GMBH	IT
Brimonidina ratiopharm 2 mg/ml collirio, soluzione	DK/H/1270/001	038671020	RATIOPHARM GMBH	IT
Brimonidina ratiopharm 2 mg/ml collirio, soluzione	DK/H/1270/001	038671032	RATIOPHARM GMBH	IT
Brimonidina ratiopharm 2 mg/ml collirio, soluzione	DK/H/1270/001	038671018	RATIOPHARM GMBH	IT
Brimonidina Sandoz 2 mg/ml collirio, soluzione	DK/H/1267/001	039016011	SANDOZ S.P.A.	IT
Brimonidina Sandoz 2 mg/ml collirio, soluzione	DK/H/1267/001	039016035	SANDOZ S.P.A.	IT
Brimonidina Sandoz 2 mg/ml collirio, soluzione	DK/H/1267/001	039016047	SANDOZ S.P.A.	IT
Brimonidina Sandoz 2 mg/ml collirio, soluzione	DK/H/1267/001	039016023	SANDOZ S.P.A.	IT
Brimonidina Sandoz 2 mg/ml collirio, soluzione	DK/H/1267/001	039016050	SANDOZ S.P.A.	IT
Brimonidin-AL 2 mg/ml Augentropfen	DK/H/1271/001	69992.00.00	ALIUD PHARMA GMBH	DE
Brimonidin-dura 2 mg/ml Augentropfen	DK/H/1264/001	76718.00.00	MYLAN DURA GMBH	DE
Brimonidine Chauvin 2 mg/ml, collyre en solution	DK/H/1268/001	34009 395 208 9 6	LABORATOIRE CHAUVIN	FR
Brimonidine Chauvin 2 mg/ml, collyre en solution	DK/H/1268/001	34009 395 209 5 7	LABORATOIRE CHAUVIN	FR
Brimonidine Chauvin 2 mg/ml, collyre en solution	DK/H/1268/001	34009 395 210 3 9	LABORATOIRE CHAUVIN	FR

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
Brimonidine Chauvin 2 mg/ml, collyre en solution	DK/H/1268/001	34009 395 212 6 8	LABORATOIRE CHAUVIN	FR
Brimonidine Chauvin 2 mg/ml, collyre en solution	DK/H/1268/001	34009 395 213 2 9	LABORATOIRE CHAUVIN	FR
BRIMONIDINE EG 0,2 % (2 mg/ml), collyre en solution	DK/H/1272/001	NL34432	EG LABO - LABORATOIRES EUROGENERICS	FR
BRIMONIDINE SANDOZ 0,2 % (2 mg/ml), collyre en solution	DK/H/1267/001	393 089-2	SANDOZ	FR
BRIMONIDINE SANDOZ 0,2 % (2 mg/ml), collyre en solution	DK/H/1267/001	393 092-3	SANDOZ	FR
BRIMONIDINE SANDOZ 0,2 % (2 mg/ml), collyre en solution	DK/H/1267/001	393 088-6	SANDOZ	FR
BRIMONIDINE SANDOZ 0,2 % (2 mg/ml), collyre en solution	DK/H/1267/001	393 090-0	SANDOZ	FR
BRIMONIDINE SANDOZ 0,2 % (2 mg/ml), collyre en solution	DK/H/1267/001	393 091-7	SANDOZ	FR
Brimonidine tartrate 2 mg/ml eye drops, solution	DK/H/1264/001	PL 04569/0853	GENERICS [UK] LIMITED	UK
Brimonidinetartaat Sandoz 2 mg/ml, oogdruppels, oplossing	DK/H/1267/001	RVG 103574	SANDOZ B.V.	NL
Brimonidinetartraat Mylan 2 mg/ml, oogdruppels (oplossing)	DK/H/1264/001	RVG 100260	MYLAN B.V.	NL
Brimonidin-HEXAL® 2 mg/ml Augentropfen Wirkstoff: Brimonidin[(R,R)]-tartrat	DK/H/1267/001	69935.00.00	HEXAL AG	DE
Brimonidin-ratiopharm® 2 mg/ml (0,2 %) Augentropfen	DK/H/1270/001	69938.00.00	RATIOPHARM GMBH	DE
Brimonidin-STADA® 2 mg/ml Augentropfen	DK/H/1272/001	69991.00.00	STADAPHARM GMBH	DE

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
Brimonidintartrat "1A Farma", øjendråber, opløsning	DK/H/1267/001	41487	1A FARMA A/S	DK
Brimonidintartrat AbZ 2 mg/ml (0,2 %) Augentropfen	DK/H/1269/001	69937.00.00	ABZ-PHARMA GMBH	DE
Brimoratio 2 mg/ml ögondroppar, lösning.	DK/H/1270/001	25601	TEVA SWEDEN AB	SE
Brimoratio 2 mg/ml øyedråper, oppløsning	DK/H/1270/001	07-4996	RATIOPHARM GMBH	NO
Brimoratio, øjendråber, opløsning	DK/H/1270/001	41490	RATIOPHARM GMBH	DK
Brimostad, øjendråber, opløsning	DK/H/1271/001	41491	STADA ARZNEIMITTEL AG	DK
Brimot 2 mg/ml kapi za oko, otopina	not available	UP/I-530-09/11-01/290	MIBE PHARMACEUTICALS D.O.O.	HR
Brimotar	DK/H/2226/001	51223	DOC GENERICI S.R.L.	DK
BRIMOTON 2 mg/ml collirio, soluzione	DK/H/2226/001	043487014	DOC GENERICI S.R.L.	IT
Brimozept 2mg/ml Augentropfen	not available	86854.00.00	MIBE GMBH ARZNEIMITTEL	DE
Brimozept, øjendråber, opløsning	DK/H/1268/001	41488	BAUSCH & LOMB UK LTD.	DK
Brymont 2 mg/ml eye drops, solution	UK_H_2110_01_E_01	13-9687	BLUMONT PHARMA LTD	NO
Brymont 2 mg/ml eye drops, solution	UK/H/2110/001	PL31103/0004	BLUMONT PHARMA LTD	UK
Brymont 2 mg/ml ögondroppar, lösning	UK/H/2110/001	49801	BLUMONT PHARMA LTD	SE
Brymont® , krople do oczu 2 mg/ml, roztwór, krople do oczu roztwór	UK/H/2110/001	18235	BLUMONT PHARMA LTD	PL
Edecol 2 mg/ml Eye drops, solution	not available	ML 21550	DELORBIS PHARMACEUTICALS LTD	CY
Glaubrim 2 mg/ml collirio, soluzione	UK/H/2110/001	040101014/M	FARMIGEA SPA	IT
Glaubrim 2 mg/ml collirio, soluzione	UK/H/2110/001	040101026/M	FARMIGEA SPA	IT

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
Glaubrim 2 mg/ml collirio, soluzione	UK/H/2110/001	040101038/M	FARMIGEA SPA	IT
Glaudin 2 mg/ml ögondroppar, lösning	DK/H/1264/001	25597	MYLAN AB	SE
Glaudin, øjendråber, opløsning	DK/H/1264/001	41485	MYLAN AB	DK
Glaudix 2 mg/ml oční kapky, roztok	NL/H/2433/001	64/147/13-C	MEDANA PHARMA SPOLKA AKCYJNA	CZ
Luxfen 2 mg/ml acu pilieni, šķīdums	CZ/H/0646/001	08-0208	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
LUXFEN 2 mg/ml akiu lašai (tirpalas)	CZ/H/0646/001	LT/1/08/1312/003	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
LUXFEN 2 mg/ml akių lašai (tirpalas)	CZ/H/0646/001	LT/1/08/1312/005	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
LUXFEN 2 mg/ml akių lašai (tirpalas)	CZ/H/0646/001	LT/1/08/1312/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
LUXFEN 2 mg/ml akių lašai (tirpalas)	CZ/H/0646/001	LT/1/08/1312/002	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
LUXFEN 2 mg/ml akių lašai (tirpalas)	CZ/H/0646/001	LT/1/08/1312/004	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Luxfen 2 mg/ml kapi za oko, otopina	not available	UP/I-530-09/12-01/317	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HR
LUXFEN 2 mg/ml ocná roztoková instilácia	CZ/H/0646/001	64/0363/08-S	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SK
LUXFEN, 2 mg/ml oční kapky, roztok	CZ/H/0646/001	64/496/08-C	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	CZ
Luxfen, 2 mg/ml, krople do oczu, roztwór	CZ/H/0646/001	15077	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
Mobridin, øjendråber, opløsning	DK/H/1269/001	41489	RATIOPHARM GMBH	DK
ЛУКСФЕН 2 mg/ml капли за очи, разтвор	CZ/H/0646/001	20080142	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG