



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2021
EMA/53162/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: latanoprost (except for products with paediatric indication)

Procedure no.: PSUSA/00001832/202104

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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
Droplatan 50 microgrammi/ml collirio, soluzione	IT/H/0401/001/DC	039874019	OMNIVISION ITALIA S.R.L.	IT
Droplatan 50 microgrammi/ml collirio, soluzione	IT/H/0401/001/DC	039874021	OMNIVISION ITALIA S.R.L.	IT
Droplatan 50 microgrammi/ml collirio, soluzione	IT/H/0401/001/DC	039874033	OMNIVISION ITALIA S.R.L.	IT
LATANOGAN 0.005% w/v Οφθαλμικές σταγόνες, διάλυμα.	not available	29426/16/04-07-2019	ZWITTER PHARMACEUTICALS ΕΠΕ	GR
Latanoprost Qualigen 50 microgramos/ml colirio en solución	not available	74.843	NEURAXPHARM SPAIN, S.L.U.	ES
Latanoprost Stulln 50 Mikrogramm/ml Augentropfen	not available	86060.00.00	PHARMA STULLN GMBH	DE
MONOPOST 50 micrograme/ml, picaturi oftalmice, solutie	FR/H/0499/002	9594/2017/01	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție	FR/H/0499/002	9594/2017/02	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/01	LABORATOIRES THEA	RO

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
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/05	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/09	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/02	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/06	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/10	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/03	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/07	LABORATOIRES THEA	RO

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
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/11	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/04	LABORATOIRES THEA	RO
MONOPOST 50 micrograme/ml, picături oftalmice, soluție în recipient unidoză	FR/H/0499/001	12283/2019/08	LABORATOIRES THEA	RO
MONOPOST 50 micrograms/ml eye drops, solution in single-dose container.	FR/H/0499/001	PL 20162/0015	LABORATOIRES THEA	XI
Monopost 50 Mikrogramm/ml Augentropfen im Einzeldosisbehältnis	FR/H/0499/001	1-31607	LABORATOIRES THEA	AT
Monopost 50 Mikrogramm/ml Augentropfen, Lösung	FR/H/0499/002	137267	LABORATOIRES THEA	AT
Monopost 50 mikrogramov/ml kapljice za oko, raztopina	FR/H/0499/002	H/13/01053/009	LABORATOIRES THEA	SI
Monopost 50 mikrogramov/ml kapljice za oko, raztopina	FR/H/0499/002	H/13/01053/010	LABORATOIRES THEA	SI

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
Monopost 50 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	FR/H/0499/001	H/13/01053/001	LABORATOIRES THEA	SI
Monopost 50 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	FR/H/0499/001	H/13/01053/002	LABORATOIRES THEA	SI
Monopost 50 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	FR/H/0499/001	H/13/01053/003	LABORATOIRES THEA	SI
Monopost 50 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	FR/H/0499/001	H/13/01053/004	LABORATOIRES THEA	SI
Monopost 50 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	FR/H/0499/001	H/13/01053/005	LABORATOIRES THEA	SI
Monopost 50 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	FR/H/0499/001	H/13/01053/006	LABORATOIRES THEA	SI
Monopost 50 mikrogramov/ml kapljice za oko, raztopina v enoodmernem vsebniku	FR/H/0499/001	H/13/01053/007	LABORATOIRES THEA	SI

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
MONOPOST 50 mikrogramov/ml očná roztoková instilácia	FR/H/0499/002	64/0501/16-S	LABORATOIRES THEA	SK
MONOPOST 50 mikrogramov/ml, očná roztoková instilácia v jednodávkovom obale.	FR/H/0499/001	64/0072/13-S	LABORATOIRES THEA	SK
MONOPOST 50 mikrogramų/ml akių lašai (tirpalas viendozėje talpyklėje)	FR/H/0499/001	LT/1/13/3236/001	LABORATOIRES THEA	LT
MONOPOST 50 mikrogramų/ml akių lašai (tirpalas viendozėje talpyklėje)	FR/H/0499/001	LT/1/13/3236/002	LABORATOIRES THEA	LT
MONOPOST 50 mikrogramų/ml akių lašai (tirpalas viendozėje talpyklėje)	FR/H/0499/001	LT/1/13/3236/003	LABORATOIRES THEA	LT
MONOPOST 50 mikrogramų/ml akių lašai (tirpalas viendozėje talpyklėje)	FR/H/0499/001	LT/1/13/3236/004	LABORATOIRES THEA	LT
Monopost 50 mikrogramů/ml oční kapky, roztok	FR/H/0499/002	64/499/16-C	LABORATOIRES THEA	CZ
Monopost 50 mikrogramů/ml oční kapky, roztok v	FR/H/0499/001	64/003/12-C	LABORATOIRES THEA	CZ

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
jednodávkovém obalu				
Monopost Unidose 50 micrograms/ml eye drops, solution in single-dose container.	FR/H/0499/001	PA1107/7/1	LABORATOIRES THEA	IE
Monopro 50 mikrogrammi/ml silmatilgad, lahus üheannuselises konteineris	FR/H/0499/001	797012	LABORATOIRES THEA	EE
Monoprost 50 microgram/ml, oogdruppels, oplossing	FR/H/0499/002	BE503822	LABORATOIRES THEA	BE
Monoprost 50 microgram/ml, oogdruppels, oplossing	FR/H/0499/002	RVG 115689	LABORATOIRES THEA	NL
Monoprost 50 microgram/ml, oogdruppels, oplossing in verpakking voor éénmalig gebruik	FR/H/0499/001	BE428635	LABORATOIRES THEA	BE
Monoprost 50 microgram/ml, oogdruppels, oplossing in verpakking voor éénmalig gebruik	FR/H/0499/001	RVG 110246	LABORATOIRES THEA	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
MONOPROST 50 microgramas/ml colírio, solução	FR/H/0499/001	5725007	LABORATOIRES THEA	PT
MONOPROST 50 microgramas/ml colírio, solução	FR/H/0499/001	5727015	LABORATOIRES THEA	PT
MONOPROST 50 microgramas/ml colírio, solução em recipiente unidose	FR/H/0499/001	5552724	LABORATOIRES THEA	PT
Monoprost 50 microgrammes/ml, collyre en solution	FR/H/0499/002	BE503822	LABORATOIRES THEA	BE
MONOPROST 50 microgrammes/ml, collyre en solution	FR/H/0499/002	34009 300 779 7 9	LABORATOIRES THEA	FR
MONOPROST 50 microgrammes/ml, collyre en solution	FR/H/0499/002	34009 300 834 6 8	LABORATOIRES THEA	FR
Monoprost 50 microgrammes/ml, collyre en solution	FR/H/0499/002	2017070236	LABORATOIRES THEA	LU
Monoprost 50 microgrammes/ml, collyre en solution en récipient unidose	FR/H/0499/001	BE428635	LABORATOIRES THEA	BE
MONOPROST 50 microgrammes/ml, collyre en solution en récipient	FR/H/0499/001	34009 267 379 5 5	LABORATOIRES THEA	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
unidose				
MONOPROST 50 microgrammes/ml, collyre en solution en récipient unidose	FR/H/0499/001	34009 267 380 3 7	LABORATOIRES THEA	FR
MONOPROST 50 microgrammes/ml, collyre en solution en récipient unidose	FR/H/0499/001	34009 267 382 6 6	LABORATOIRES THEA	FR
MONOPROST 50 microgrammes/ml, collyre en solution en récipient unidose	FR/H/0499/001	34009 583 657 1 3	LABORATOIRES THEA	FR
Monoprost 50 microgrammes/ml, collyre en solution en récipient unidose	FR/H/0499/001	2013010029	LABORATOIRES THEA	LU
MONOPROST 50 microgrammi/ml collirio soluzione in contenitore monodose.	FR/H/0499/001	41429010	LABORATOIRES THEA	IT
MONOPROST 50 microgrammi/ml collirio soluzione in contenitore monodose.	FR/H/0499/001	41429022	LABORATOIRES THEA	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
MONOPROST 50 microgrammi/ml collirio soluzione in contenitore monodose.	FR/H/0499/001	41429034	LABORATOIRES THEA	IT
MONOPROST 50 microgrammi/ml collirio soluzione in contenitore monodose.	FR/H/0499/001	41429046	LABORATOIRES THEA	IT
MONOPROST 50 microgrammi/ml collirio, soluzione	not available	041429059	LABORATOIRES THEA	IT
MONOPROST 50 microgrammi/ml collirio, soluzione	not available	041429061	LABORATOIRES THEA	IT
Monoprost 50 microgramos/ml colirio en solución en envase unidosis.	FR/H/0499/001	76616	LABORATOIRES THEA	ES
Monoprost 50 microgramos/ml colirio en solución.	not available	82878	LABORATOIRES THEA	ES
Monoprost 50 mÍkróg/ml augndropar, lausn	FR/H/0499/002	IS/1/16/103/01	LABORATOIRES THEA	IS
Monoprost 50 mikrog/ml silmätipat, liuos	FR/H/0499/002	32408	LABORATOIRES THEA	FI

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
Monoprost 50 mikrog/ml silmätipat, liuos, kerta-annospakkaus.	FR/H/0499/001	30049	LABORATOIRES THEA	FI
Monoprost 50 mikrogram/ml ögondroppar, lösning	FR/H/0499/002	32408	LABORATOIRES THEA	FI
Monoprost 50 mikrogram/ml ögondroppar, lösning	FR/H/0499/002	51352	LABORATOIRES THEA	SE
Monoprost 50 mikrogram/ml øyedråper, oppløsning	FR/H/0499/002	14-10179	LABORATOIRES THEA	NO
Monoprost 50 mikrogram/ml øyedråper, oppløsning i endosebeholder	FR/H/0499/001	11-8494	LABORATOIRES THEA	NO
Monoprost 50 mikrogram/ml, ögondroppar, lösning i endosbehållare	FR/H/0499/001	30049	LABORATOIRES THEA	FI
Monoprost 50 mikrogram/ml, ögondroppar, lösning i endosbehållare.	FR/H/0499/001	46521	LABORATOIRES THEA	SE
Monoprost 50 mikrogrami/ml acu pilieni, šķīdums vienas devas iepakojumā	FR/H/0499/001	12-0277	LABORATOIRES THEA	LV

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
MONOPROST 50 Mikrogramm/ml Augentropfen, Lösung	FR/H/0499/002	91910.00.00	LABORATOIRES THEA	DE
Monoprost 50 Mikrogramm/ml Augentropfen, Lösung im Einzeldosisbehältnis	FR/H/0499/001	BE428635	LABORATOIRES THEA	BE
MONOPROST 50 Mikrogramm/ml Augentropfen, Lösung im Einzeldosisbehältnis	FR/H/0499/001	85424.00.00	LABORATOIRES THEA	DE
Monoprost 50 Mikrogramm/ml, Augentropfen, Lösung	FR/H/0499/002	BE503822	LABORATOIRES THEA	BE
Monoprost 50 Mikrogramm/ml, Augentropfen, Lösung	FR/H/0499/002	2017070236	LABORATOIRES THEA	LU
MONOPROST 50 míkrógrömm/ml augndropar, lausn í stakskammtailáti	FR/H/0499/001	IS/1/12/106/01	LABORATOIRES THEA	IS
MONOPROST 50 μικρογραμμάρια/ml οφθαλμικές σταγόνες, διάλυμα	FR/H/0499/001	022828	LABORATOIRES THEA	CY
MONOPROST 50 μικρογραμμάρια/ml οφθαλμικές σταγόνες, διάλυμα	FR/H/0499/002	51038/08.06.2017	LABORATOIRES THEA	GR

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
MONOPROST 50 μικρογραμμάρια/ml οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης	FR/H/0499/001	021947	LABORATOIRES THEA	CY
MONOPROST 50 μικρογραμμάρια/ml οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης.	FR/H/0499/001	23708/22-03-2013	LABORATOIRES THEA	GR
MONOPROST, 50 mikrogramów/ml, krople do oczu, roztwór	FR/H/0499/002	23857	LABORATOIRES THEA	PL
MONOPROST, 50 mikrogramów/ml, krople do oczu, roztwór w pojemniku jednodawkowym	FR/H/0499/001	20654	LABORATOIRES THEA	PL
Monoprost, øjendråber, opløsning	FR/H/0499/002	54570	LABORATOIRES THEA	DK
Monoprost, øjendråber, opløsning, enkeltdosisbeholder	FR/H/0499/001	49449	LABORATOIRES THEA	DK
OCUSYNT 50 microgrammi/ml collirio, soluzione	not available	038612038	GENETIC 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
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
VLEPOLIN 0,005% Οφθαλμικές σταγόνες, διάλυμα	not available	3042001	DEMO ABEE	GR
XALIBUR 50 microgrammi/ml collirio, soluzione	not available	038611024	PFIZER ESTABLISHED MEDICINE ITALY S.R.L.	IT
XALIBUR 50 microgrammi/ml collirio, soluzione in contenitore monodose	not available	038611036	PFIZER ESTABLISHED MEDICINE ITALY S.R.L.	IT
ΜΟΝΟΠΡΟΣΤ 50 микрограма/ml капки за очи, разтвор в еднодозова опаковка.	FR/H/0499/001	20130076	LABORATOIRES THEA	BG
ΜΟΝΟΠΡΟΣΤ 50 микрограма/ml капки за очи, разтвор.	FR/H/0499/002	20170102	LABORATOIRES THEA	BG