



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2016
EMA/361720/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: latanoprost (products with paediatric indication)

Procedure no.: PSUSA/00001834/201510



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
Akistan	SE/H/1095/01/DC	1-31279	Pharmaselect International Beteiligungs Gmbh	Austria
Akistan	SE/H/1095/01/DC	20362	Pharmaselect International Beteiligungs Gmbh	Poland
Akistan	SE/H/1095/01/DC	45460	Pharmaselect International Beteiligungs Gmbh	Sweden
Akistan	SE/H/1095/01/DC	5363-I-2366/12	Pharmaselect International Beteiligungs Gmbh	Slovenia
Akistan	SE/H/1095/01/DC	5453/2013/01	Pharmaselect International Beteiligungs Gmbh	Romania
Akistan	SE/H/1095/001/DC	64/387/12-C	Pharmaselect International Beteiligungs Gmbh	Czech Republic
Akistan	SE/H/1095/01/DC	780312	Pharmaselect International Beteiligungs Gmbh	Estonia
Akistan	SE/H/1095/01/DC	84058.00.00	Pharmaselect International Beteiligungs Gmbh	Germany
Akistan	SE/H/1095/01/DC	LT/1/12/2952/001	Pharmaselect International Beteiligungs Gmbh	Lithuania
Akistan	SE/H/1095/01/DC	OGYI-T-22248/01-02-03	Pharmaselect International Beteiligungs Gmbh	Hungary

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
Akistan	SE/H/1095/01/DC	12-0092	Pharmaselect International Beteiligungs Gmbh	Latvia
Akistan	SE/H/1095/01/DC	64/0080/13-s	Pharmaselect International Beteiligungs Gmbh	Slovakia
Ciptan	UK/H/5632/001/DC	OGYI-T-22859/01 \$ OGYI-T-22859/02 \$ OGYI-T-22859/03	Cipla Europe Nv	Hungary
Glaukodoc	AT/H/0404/001	1-31642	Germania Pharmazeutika Gesellschaft M.B.H.	Austria
Latacris	IE/H/0216/001	290510101	Ph&t S.P.A.	Greece
Latacris	IE/H/0216/001	PA 1604/1/1	Ph&t S.P.A.	Ireland
Latacris	IE/H/0216/001	PL 14998/0008	Ph&t S.P.A.	United Kingdom
Latacris	IE/H/0216/001/DC	18946	Sun-Farm Sp. Z.O.O. (Kolbiel)	Poland
Latacris		1-31792	Dermapharm Gmbh	Austria

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
Lataniston		3196	Novendia Pharmaceuticals Ltd	Greece
Latanomed	IE/H/0216/001	80004.00.00	Mibe Gmbh Arzneimittel	Germany
Latanoprost	UK/H/4549/001	PL 35638 /0003	Fdc Pharma	United Kingdom
Latanoprost	UK/H/4549/01/DC	34009 223 630 4 2 & 34009 223 631 0 3 & 34009 223 632 7 1	Fdc Pharma	France
Latanoprost 1 A Pharma	DE/H/2076/001	75073.00.00	1 A Pharma Gmbh	Germany
Latanoprost AbZ		86005.00.00	AbZ-Pharma GmbH	Germany
Latanoprost Actavis	NL/H/1382/001/DC	71098	Actavis Group Ptc Ehf.	Spain
Latanoprost Al	NL/H/1810/001	79742.00.00	Aliud Pharma Gmbh	Germany
Latanoprost Arrow	PL/H/0386/001	RVG 101423	Arrow Generics Limited	Netherlands

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
Latanoprost Arrow	PL/H/0386/001	70721	Arrow Generics Limited	Spain
Latanoprost Arrow	PL/H/0386/001	NL 35113	Arrow Génériques (Aurobindo)	France
Latanoprost Arrow Actavis Group Ptc Ehf.	PL/H/0386/001	15640	Actavis Group Ptc Ehf.	Poland
Latanoprost Cf	NL/H/1809/001	RVG 105910	Centrafarm B.V.	Netherlands
Latanoprost Ciclum	NL/H/1809/001	5371103 \$ 5371117	Ciculum Farma Unipessoal Ida.	Portugal
Latanoprost Cipla	UK/H/5632/01/DC	50671	Cipla Europe Nv	Sweden
Latanoprost Cipla	UK/H/5632/01/DC	53672	Cipla Europe Nv	Denmark
Latanoprost Cipla	UK/H/5632/01/DC	64/0335/15-S	Cipla Europe Nv	Slovakia
Latanoprost Cipla	UK/H/5632/01/DC	HR-H-629561233-01 \$ HR-H-629561233-02 \$ HR-H-629561233-03	Cipla (Eu) Limited	Croatia

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
Latanoprost Cipla	UK/H/5632/01/DC	881615	Cipla Europe Nv	Estonia
Latanoprost Cipla	UK/H/5632/01/DC	RVG 114785	Cipla Europe Nv	Netherlands
Latanoprost Cipla	UK/H/5632/01/DC	13-9930	Cipla Europe Nv	Norway
Latanoprost Cipla	UK/H/5632/01/DC	BE478417	Cipla Europe Nv	Belgium
Latanoprost Cipla	UK/H/5632/01/DC	32047	Cipla Europe Nv	Finland
Latanoprost Cipla (Eu)	UK/H/5632/01/DC	PA 1809/013/001	Cipla (Eu) Limited	Ireland
Latanoprost Cipla (Eu)	UK/H/5632/01/DC	PL 36390/0173	Cipla (Eu) Limited	United Kingdom
Latanoprost Cipla 50 Mikrogramm/ml Augentropfen	UK/H/5632/01/DC	136568	Cipla Europe Nv	Austria
Latanoprost Demo	UK/H/5496/001	91614.00.00	Demo S.A.	Germany

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
Latanoprost Eg	NL/H/1809/001	2012030044	Eurogenerics Sa	Luxembourg
Latanoprost EG	NL/H/1809/001	BE381525	Eurogenerics Sa	Belgium
Latanoprost EG	NL/H/1809/001	NL 38465	Eg Labo - Laboratoires Eurogenerics	France
Latanoprost EG	NL/H/1810/001	79742.00.00	Aliud Pharma Gmbh	Germany
Latanoprost FDC Pharma	UK/H/4549/001	76568	Fdc Pharma	Spain
Latanoprost FDC Pharma	UK/H/4549/001	84694.00.00	Fdc Pharma	Germany
Latanoprost Generics [uk]	SE/H/1283/001	PA0405/068/001	Generics [uk] Limited	Ireland
Latanoprost Generics [uk]	SE/H/1283/001	PL 04569/1499	Generics [uk] Limited	United Kingdom
Latanoprost Hexal	DE/H/2075/001 \$ DE/H/2076/001	75071.00.00 \$ 75611.00.00	Hexal Ag	Germany

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
Latanoprost Kern Pharma	NL/H/1405/001	71.100	Kern Pharma, S.L.	Spain
Latanoprost Malcosa	DE/H/1999/001	75006.00.00	Malcosa Ltd	Germany
Latanoprost Mylan	SE/H/1283/001	13-9428	Mylan Ab	Norway
Latanoprost Mylan	SE/H/1283/001	2014120388	Mylan Bvba/Sprl	Luxembourg
Latanoprost Mylan	SE/H/1283/001	48953	Mylan Ab	Sweden
Latanoprost Mylan	SE/H/1283/001	52020	Mylan Ab	Denmark
Latanoprost Mylan	SE/H/1283/001	5630538 \$ 5630546 \$ 5630553	Mylan, Lda	Portugal
Latanoprost Mylan	SE/H/1283/001	64/0223/14-S	Generics [uk] Limited	Slovakia
Latanoprost Mylan	SE/H/1283/001	64/294/14-C	Generics [uk] Limited	Czech Republic

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
Latanoprost Mylan	SE/H/1283/001	78805	Mylan Pharmaceuticals S.L.	Spain
Latanoprost Mylan	SE/H/1283/001	BE458871	Mylan Bvba/Sprl	Belgium
Latanoprost Mylan	SE/H/1283/001	IS/1/14/041/01	Mylan Ab	Iceland
Latanoprost Mylan	SE/H/1283/001	RVG 113160	Mylan B.V.	Netherlands
Latanoprost Mylan	SE/H/1283/1/DC	042620017 \$ 042620029 \$ 042620031	Mylan S.p.A.	Italy
Latanoprost Noridem Enterprises	UK/H/5496/001/DC	PL 24598/0045	Noridem Enterprises Ltd	United Kingdom
Latanoprost Normon	DE/H/1999/001	72101	Laboratorios Normon, S.A.	Spain
Latanoprost Pfizer	National procedure	OGYI-T-21936/01 \$ OGYI-T-21936/02	Pfizer Kft.	Hungary
Latanoprost Pharmacia und Upjohn		42589.00.00	Pharmacia GmbH	Germany

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
Latanoprost Ranbaxy	NL/H/2052/001	NL 40087	Ranbaxy Pharmacie Generiques	France
Latanoprost Ranbaxy	NL/H/2052/001/DC	RVG 107731	Ranbaxy (Uk) Limited	Netherlands
Latanoprost Ratiopharm	NO/H/0139/001	0687/10040028	Ratiopharm Gmbh	Luxembourg
Latanoprost Ratiopharm	NO/H/0139/001	07-5388	Ratiopharm Gmbh	Norway
Latanoprost Ratiopharm	NO/H/0139/001	09-0121	Ratiopharm Gmbh	Latvia
Latanoprost Ratiopharm	NO/H/0139/001	1-28392	Ratiopharm Arzneimittel Vertriebs-Gmbh	Austria
Latanoprost Ratiopharm	NO/H/0139/001	24330	Ratiopharm Gmbh	Finland
Latanoprost Ratiopharm	NO/H/0139/001	626609	Ratiopharm Gmbh	Estonia
Latanoprost Ratiopharm	NO/H/0139/001	64/237/09-C	Ratiopharm Gmbh	Czech Republic

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
Latanoprost Ratiopharm	NO/H/0139/001	71970.00.00	Ratiopharm Gmbh	Germany
Latanoprost Ratiopharm	NO/H/0139/001	LT/1/09/1544/001 \$ LT/1/09/1544/002 \$ LT/1/09/1544/003	Ratiopharm Gmbh	Lithuania
Latanoprost Sandoz	DE/H/2076/001	08-6413	Sandoz A/S	Norway
Latanoprost Sandoz	DE/H/2076/001	1-30546	Sandoz Gmbh	Austria
Latanoprost Sandoz	DE/H/2076/001	27104	Sandoz A/S	Finland
Latanoprost Sandoz	DE/H/2076/001	41820	Sandoz A/S	Sweden
Latanoprost Sandoz	DE/H/2076/001	44410	Sandoz A/S	Denmark
Latanoprost Sandoz	DE/H/2076/001	74523	Sandoz Farmacéutica, S.A.	Spain
Latanoprost Sandoz	DE/H/2076/001	BE393985	Sandoz N.V.	Belgium

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
Latanoprost Sandoz	DE/H/2076/001	PL 04416/1051	Sandoz Ltd	United Kingdom
Latanoprost Sandoz	DE/H/2076/001	RVG 104079	Sandoz B.V.	Netherlands
Latanoprost Sanoswiss		LT/1/11/2468/001-002	Sanoswiss UAB	Lithuania
Latanoprost Stada	NL/H/1408/001	71.103	Laboratorio Stada, S.L.	Spain
Latanoprost Stada	NL/H/1809/001	1-30255	Stada Arzneimittel Gmbh	Austria
Latanoprost Stada	NL/H/1809/001	18283	Stada Arzneimittel Ag	Poland
Latanoprost Stada	NL/H/1809/001	43052	Stada Arzneimittel Ag	Sweden
Latanoprost Stada	NL/H/1809/001	45622	Stada Arzneimittel Ag	Denmark
Latanoprost Stada	NL/H/1809/001	79707.00.00	Stadapharm Gmbh	Germany

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
Latanoprost Stada	NL/H/1810/001	RVG 105912	Stada Arzneimittel Ag	Netherlands
Latanoprost Stada	NL/H/3195/001	64/382/15-C	Stada Arzneimittel Ag	Czech Republic
Latanoprost Stada Hf	NL/H/1809/001	3466/2011/01-02-03	Stada Hemofarm S.R.L.	Romania
Latanoprost Teva	NO/H/0139/001	26305	Teva Sweden Ab	Sweden
Latanoprost Teva	NO/H/0139/001	5436647	Teva Pharma – Produtos Farmacêuticos Lda	Portugal
Latanoprost Teva	NO/H/0139/001	71221	Teva Pharma S.L.U	Spain
Latanoprost Teva	NO-H-0139-001	42427	Teva Denmark A/S	Denmark
Latanoprost Teva	NO-H-0139-001	41663/23-6-2015	Teva Pharma B.V.	Greece
Latanoprost Teva	NO-H-0139-001	PA0749/173/001	Teva Pharma B.V.	Ireland

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
Latanoprost Teva	NO-H-0139-001	RVG 101418	Teva Nederland B.V.	Netherlands
Latanoprost Teva Uk	NO/H/0139/001	PL 00289/1668	Teva Uk Limited	United Kingdom
Latanoprost Trb	AT/H/0406/001	1-31644	Pharmavision Gmbh	Austria
Latanoprost Trb		84610.00.00	Trb Chemedica Ag	Germany
Latanoprost Unimed Pharma 50 Mikrogramm/ml Augentropfen	SK/H/0107/001/E/001	1-31790	Unimed Pharma spol sro	Austria
Latanoprost Unimed Pharma 50 mikrogramov/ml kapljice za oko, raztopina	SK/H/0107/001/E/001	5363-I-669/13 \$ 5363-I-670/13	Unimed Pharma spol sro	Slovenia
Latanoprost-FDC Pharma	UK/H/4549/01/DC	040895017/M;040895029/M;040895031/M	Fdc Pharma	Italy
Latanoprost-Pos Ursapharm Benelux	NL/H/1875/001	RVG 106487	Ursapharm Benelux B.V.	Netherlands
Latanoprostum Cipla	UK/H/5632/01/DC	15-0278	Cipla Europe Nv	Latvia

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
Latanostad Stada	NL/H/3195/001	RVG 115407	Stada Arzneimittel Ag	Netherlands
Latano-Vision	AT/H/0450/001/DC	1-30741	Omnivision Gmbh	Austria
Latano-Vision	AT/H/0450/001/DC	82805.00.00	Omnivision Gmbh	Germany
Latizolil	DE/H/2076/001	11-0109	Sandoz Pharmaceuticals D.D.	Latvia
Latop	DE/H/2075/001	PA 711/177/1	Rowex Ltd	Ireland
Oftastad	NL/H/1809/001	27906	Stada Arzneimittel Ag	Finland
Pharmaprost	DE/H/1999/001	12137/3-2-14	Pharmex S.A.	Greece
Pharmecol	DE/H/1999/001	20753	Pharmex S.A.	Cyprus
Polprost	DE/H/2076/001	18344	Sandoz Gmbh	Poland

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
Proxal	PL/H/0386/001	PA 1380/161/1	Actavis Group Ptc Ehf.	Ireland
Rozaprost Mono	NL/H/2589/001	21703	Adamed	Poland
Tonlit		73820	Laboratorios Salvat, S.A.	Spain
Xalatan	UK/H/0179/001	1-22019	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Xalatan	UK/H/0179/001	BE183967	Pfizer S.A. (Belgium)	Belgium
Xalatan		UP/I-530-09/11-02/198	Pfizer Croatia D.O.O.	Croatia
Xalatan	UK/H/0179/001	20805/22-11-2010	Pfizer Hellas, A.E.	Cyprus
Xalatan		64/164/99-C	Pfizer, Spol. S R.O.	Czech Republic
Xalatan	UK/H/0179/001	18752	Pfizer Aps	Denmark

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
Xalatan		284899	Pfizer Enterprises Sarl	Estonia
Xalatan	UK/H/0179/001	12694	Pfizer Oy	Finland
Xalatan	UK/H/0179/001	NL 22 549	Pfizer Holding France (S.C.A.)	France
Xalatan	UK/H/0179/001	40466.00.00	Pharmacia Gmbh	Germany
Xalatan	UK/H/0179/001	32620/07/11-04-2008	Pfizer Hellas, A.E.	Greece
Xalatan	National procedure	OGYI-T- 5637/02 \$ OGYI-T-5637/01	Pfizer Kft.	Hungary
Xalatan		980195	Pfizer Aps	Iceland
Xalatan	UK/H/0179/001	PA 0822/140/001	Pfizer Healthcare Ireland	Ireland
Xalatan	UK/H/0179/001	033219015 \$ 033219027	Pfizer Italia S.R.L.	Italy

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
Xalatan		00-0502	Pfizer Europe Ma Eeig	Latvia
Xalatan		LT/1/99/0417/001	Pfizer Europe Ma Eeig	Lithuania
Xalatan	UK/H/0179/001	2009060447	Pfizer S.A. (Belgium)	Luxembourg
Xalatan		505/02501	Pfizer Hellas, A.E.	Malta
Xalatan	UK/H/0179/001	RVG 21304	Pfizer B.V.	Netherlands
Xalatan		95-2153	Pfizer As	Norway
Xalatan		4118	Pfizer Europe Ma Eeig	Poland
Xalatan	UK/H/0179/001	2547388 \$ 2547487 \$ 5226832 \$ 5226840 \$ 5226857	Laboratórios Pfizer, Lda.	Portugal
Xalatan		7107/2014/01 \$ 7107/2014/02 \$ 7107/2014/03 \$ 7107/2014/04	Pfizer Europe Ma Eeig	Romania

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
Xalatan		64/0121/98-S	Pfizer Europe Ma Eeig	Slovakia
Xalatan		5363-I-2431/10	Pfizer Luxembourg Sarl	Slovenia
Xalatan	UK/H/0179/001	61.756	Pfizer, S.L.	Spain
Xalatan		12716	Pfizer Ab	Sweden
Xalatan	UK/H/0179/001	PL 00057/1057	Pfizer Limited	United Kingdom
Xalibur		38611036	Pfizer Italia S.R.L.	Italy
Xaloptic	NL/H/3193/001	RVG 115290	Zakłady Farmaceutyczne "polpharma" Spolka Akcyjna	Netherlands
Xaloptic Free	NL/H/3193/001	22424	Zakłady Farmaceutyczne "polpharma" Spolka Akcyjna	Poland
Xalost	DE/H/1999/001	039795012 \$ 039795024 \$ 039795036	Farmigea Spa	Italy

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
Zakoprost		46828/ 25-09-2013	Pharmazac Sa	Greece
акистан	SE/H/1095/01/DC	20130062	Pharmaselect International Beteiligungs Gmbh	Bulgaria
ксалатан		9900241	Pfizer Enterprises Sarl	Bulgaria
латанопрост сипла	UK/H/5632/01/DC	20150294	Cipla Europe Nv	Bulgaria
ЛАТАЛУКС 50 микрограма/ml капки за очи, разтвор	NL/H/1654/001/DC	20100633	PharmaSwiss Česká republika s.r.o	Bulgaria
LATALUX 50 mikrogramů/ml oční kapky, roztok	NL/H/1654/001/DC	64/584/10-C	PharmaSwiss Česká republika s.r.o	Czech Republic
LATALUX 50 mikrogrami/ml acu pilieni, šķīdums	NL/H/1654/001/DC	10-0502	PharmaSwiss Česká republika s.r.o	Latvia
LATALUX 50 mikrogramų/ml akių lašai, (tirpalas)	NL/H/1654/001/DC	LT/1/10/2163/001-003	PharmaSwiss Česká republika s.r.o	Lithuania
LATALUX 50 microgram/ml oogdruppels, oplossing	NL/H/1654/001/DC	RVG 104319	Pharmaceutical Company Jelfa S.A.	Netherlands

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
LATALUX	NL/H/1654/001/DC	17247	PharmaSwiss Česká republika s.r.o	Poland
LATALUX 50 mikrogramov/ml očná roztoková instilácia	NL/H/1654/001/DC	64/0474/10-S	PharmaSwiss Česká republika s.r.o	Slovakia