



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 November 2015
EMA/761710/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: latanoprost (products with paediatric indication)

Procedure no.: PSUSA/00001834/201504



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/1095/01/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-22248/0	Pharmaselect International Beteiligungs Gmbh	Hungary
Exprosol 50 microgram/ml oogdruppels, oplossing	NL/H/1408/001	RVG 102640	STADA Arzneimittel AG	Netherlands

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Glaukodoc	AT/H/404/001/DC	1-31642	Germania Pharmazeutika Gesellschaft M.B.H.	Austria
Latacris		1-31792	Dermapharm Gmbh	Austria
Latacris	IE/H/0216/001	18946	Sun-Farm Sp. Z.O.O. (Kolbiel)	Poland
Latacris	IE/H/0216/001	290510101 \$ 290510102 \$ 290510103	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
Lataniston	Purely National	3196/16-1-2012	Novendia Pharmaceuticals Ltd	Greece
Latano-Pos	NL/H/1875/001/DC	20055	Ursapharm Poland Sp. Z. O.O.	Poland
Latano-Vision	AT/H/0450/001	1-30741	Omnivision Gmbh	Austria
Latano-Vision	AT/H/0450/001	82805.00.00	Omnivision Gmbh	Germany
Latanomed	IE/H/0216/001	80004.00.00	Mibe Gmbh Arzneimittel	Germany

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Latanoprost 1 A Pharma	DE/H/2074/001 \$ DE/H/2076/001	75052.00.00 \$ 75073.00.00	1 A Pharma Gmbh	Germany
Latanoprost Aliud Pharma	NL/H/1810/001	79742.00.00	Aliud Pharma Gmbh	Germany
Latanoprost Ciclum	NL/H/1809/001	5371109 \$ 5371117	Ciculum Farma Unipessoal, Lda	Portugal
Latanoprost Eg Labo Laboratoires Eurogenerics	NL/H/1809/001	3400941619410 \$ 3400941619588 \$ 3400941619649	Eg Labo - Laboratoires Eurogenerics	France
Latanoprost Eurogenerics	NL/H/1809/001	2012030044	Eurogenerics Sa	Luxembourg
Latanoprost Eurogenerics	NL/H/1809/001	BE381525	Eurogenerics Sa	Belgium
Latanoprost Hexal	DE/H/2075/001 \$ DE/H/2076/001	75071.00.00 \$ 75611.00.00	Hexal Ag	Germany
Latanoprost Kern Pharma	NL/H/1405/001	71.100	Kern Pharma, S.L.	Spain
Latanoprost Malcosa	DE/H/1999/001/R/001	75006.00.00	Malcosa Ltd	Germany
Latanoprost Normon	DE/H/1999/001/DC	72101	Laboratorios Normon, S.A.	Spain
Latanoprost Oogdruppels Cf	NL/H/1809/001	RVG 105910	Centrafarm B.V.	Netherlands

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Latanoprost Oogdruppels Stada	NL/H/1810/001	RVG 105912	Stada Arzneimittel Ag	Netherlands
Latanoprost Pfizer		OGYI-T-21936/01 \$ OGYI-T-21936/02	Pfizer Kft.	Hungary
Latanoprost pfizer 50 Mikrogramm/ml Augentropfen	DE/H/2915/001	1-30982	pfizer Corp. Austria GmbH	Austria
Latanoprost Pfizer® 50 Mikrogramm/ml Augentropfen	DE/H/2915/001/DC	82525.00.00	Pfizer Pharma GmbH	Germany
Latanoprost Pharmacia & Upjohn		42589.00.00	Pharmacia GmbH	Germany
Latanoprost Pos	NL/H/1875/001/DC	6 443 023 5	Ursapharm Arzneimittel GmbH	France
Latanoprost Pos	NL/H/1875/001/DC	64/829/11-C	Ursapharm Spol. S.R.O.	Czech Republic
Latanoprost Premier- Research Stada Arzneimittel	NL/H/1809/001	18283	Stada Arzneimittel Ag	Poland
Latanoprost Ranbaxy	NL/H/2052/001	NL 40087	Ranbaxy Pharmacie Generiques	France
Latanoprost Ranbaxy	NL/H/2052/001	RVG 107731	Ranbaxy (Uk) Limited	Netherlands

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Latanoprost Ranbaxy	NL/H/2052/001/DC	NL 40087	Ranbaxy Pharmacie Generiques	France
Latanoprost Ranbaxy	NL/H/2052/001/DC	RVG 107731	Ranbaxy (Uk) Limited	Netherlands
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
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	Uab Sanoswiss	Lithuania

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Latanoprost STADA 50 microgramos/ml colirio en solución	NL/H/1408/001	71.103	Laboratorio STADA, S.L.	Spain
Latanoprost Stada Arzneimittel	NL/H/1809/001	1-30255	Stada Arzneimittel Gmbh	Austria
Latanoprost Stada Arzneimittel	NL/H/1809/001	43052	Stada Arzneimittel Ag	Sweden
Latanoprost Stada Arzneimittel	NL/H/1809/001	45622	Stada Arzneimittel Ag	Denmark
Latanoprost Stada Hemofarm	NL/H/1809/001	3466/2011/01-02-03	Stada Hemofarm S.R.L.	Romania
Latanoprost Stadapharm	NL/H/1809/001	79707.00.00	Stadapharm Gmbh	Germany
Latanoprost Trb	AT/H/0406/001/DC	1-31644	Pharmavision Gmbh	Austria
Latanoprost Trb	AT/H/0406/001/DC	84610.00.00	Trb Chemedica Ag	Germany
Latanoprost-Pos	NL/H/1875/001/DC	RVG 106487	Ursapharm Benelux B.V.	Netherlands
Latizolil	DE/H/2076/001	11-0109	Sandoz Pharmaceuticals D.D.	Latvia
Latop	DE/H/2075/001	PA 711/177/1	Rowex Ltd	Ireland

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Oftastad	NL/H/1809/001	27906	Stada Arzneimittel Ag	Finland
Pharmaprost	DE/H/1999/01/DC	12137/3-2-2014	PHARMEX S.A.	Greece
Pharmecol	DE/H/1999/01/DC	20753	PHARMEX S.A.	Cyprus
Polprost	DE/H/2076/001	18344	Sandoz Gmbh	Poland
Rozaprost Mono	NL/H/2589/001	21703	Adamed	Poland
Tonlit		73820	Laboratorios Salvat, S.A.	Spain
Xalatan		00-0502	Pfizer Europe Ma Eeig	Latvia
Xalatan		12716	Pfizer Ab	Sweden
Xalatan		284899	Pfizer Enterprises Sarl	Estonia
Xalatan		4118	Pfizer Europe Ma Eeig	Poland
Xalatan		505/02501	Pfizer Hellas, A.E.	Malta

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Xalatan		5363-I-2431/10	Pfizer Luxembourg Sarl	Slovenia
Xalatan		64/0121/98-S	Pfizer Europe Ma Eeig	Slovakia
Xalatan		64/164/99-C	Pfizer, Spol. S R.O.	Czech Republic
Xalatan		7107/2014/01 \$ 7107/2014/02 \$ 7107/2014/03 \$ 7107/2014/04	Pfizer Europe Ma Eeig	Romania
Xalatan		95-2153	Pfizer As	Norway
Xalatan		980195 (IS)	Pfizer Aps	Iceland
Xalatan		LT/1/99/0417/001	Pfizer Europe Ma Eeig	Lithuania
Xalatan		OGYI-T- 5637/02 \$ OGYI-T- 5637/01	Pfizer Kft.	Hungary
Xalatan		UP/I-530-09/11-02/198	Pfizer Croatia D.O.O.	Croatia
Xalatan	UK/H/0179/001	033219015 \$ 033219027	Pfizer Italia S.R.L.	Italy
Xalatan	UK/H/0179/001	1-22019	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria

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Xalatan	UK/H/0179/001	12694	Pfizer Oy	Finland
Xalatan	UK/H/0179/001	18752	Pfizer Aps	Denmark
Xalatan	UK/H/0179/001	2009060447	Pfizer Manufacturing Belgium Nv	Luxembourg
Xalatan	UK/H/0179/001	2009060447	Pfizer S.A. (Belgium)	Luxembourg
Xalatan	UK/H/0179/001	20805/22-11-2010	Pfizer Hellas, A.E.	Cyprus
Xalatan	UK/H/0179/001	2547388 \$ 2547487 \$ 5226832 \$ 5226840 \$ 5226857	Laboratórios Pfizer, Lda.	Portugal
Xalatan	UK/H/0179/001	32620/07/11-04-2008	Pfizer Hellas, A.E.	Greece
Xalatan	UK/H/0179/001	34009 343840 6 6 \$ 34009 343841 2 7	Pfizer Holding France (S.C.A.)	France
Xalatan	UK/H/0179/001	40466.00.00	Pharmacia Gmbh	Germany
Xalatan	UK/H/0179/001	61.756	Pfizer, S.L.	Spain
Xalatan	UK/H/0179/001	BE183967	Pfizer Nv	Belgium

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Xalatan	UK/H/0179/001	BE183967	Pfizer S.A. (Belgium)	Belgium
Xalatan	UK/H/0179/001	PA 822/140/1	Pfizer Healthcare Ireland	Ireland
Xalatan	UK/H/0179/001	PL 00057/1057	Pfizer Limited	United Kingdom
Xalatan	UK/H/0179/001	RVG 21304	Pfizer B.V.	Netherlands
Xalibur		038611024 \$ 038611036	Pfizer Italia S.R.L.	Italy
Xaloptic	NL/H/3193/001	RVG 115290	Zakłady Farmaceutyczne "polpharma" Spolka Akcyjna	Netherlands
Xalost	DE/H/1999/001	039795012 \$ 039795024 \$ 039795036	Farmigea Spa	Italy
Zakoprost	Purely National	46828/ 25-09-2013	Pharmazac Sa	Greece
ксалатан		9900241	Pfizer Enterprises Sarl	Bulgaria
Latanoprost Unimed Pharma	SK/H/0107/01/E/01	5363-I-669/13 \$ 5363-I-670/13	UNIMED PHARMA, spol. s r.o	Slovenia
Latanoprost Sandoz	DE/H/2076/001	08-6413	Sandoz A/S	Norway

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Latanoprost Unimed Pharma	SK/H/0107/001/E/001	1-31790	UNIMED PHARMA, spol. s r.o	Austria
Latanoprost	UK/H/5496/01/DC	PL 24598/0045	Noridem Enterprises Ltd	United Kingdom
Latanoprost	UK/H/5496/01/DC	91614.00.00	DEMO S.A.	Germany