



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 November 2016
EMA/863720/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dorzolamide

Procedure no.: PSUSA/00003168/201602

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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
Arzolid	UK/H/3137/001	45410	Actavis Group Ptc Ehf.	Denmark
Domide	UK/H/3137/001	21783	Actavis Group Ptc Ehf.	Cyprus
Domide	UK/H/3137/001	MA628/07401	Actavis Group Ptc Ehf.	Malta
Dorzolapt	AT/H/0546/001	1-30561	Dermapharm Gmbh	Austria
Dorzolapt	AT/H/0546/001	83372.00.00	Mibe Gmbh Arzneimittel	Germany
Dorzo-Vision	DK/H/1534/001/DC	1-28927	Omnivision Gmbh	Austria
Dorzo-Vision	DK/H/1534/001/DC	74991.00.00	Omnivision Gmbh	Germany
Dorzo-Vision Sine	AT/H/0561/001/DC	136729	Omnivision Gmbh	Austria
Dorzo-Vision Sine	AT/H/0561/001/DC	92490.00.00	Omnivision Gmbh	Germany
Dorzolamid Actavis	UK/H/3137/001	27733	Actavis Group Ptc Ehf.	Finland
Dorzolamide Hydrochloride	UK/H/3138/001	79119.00.00	Aliud Pharma Gmbh	Germany
Dorzolamid Hormosan	UK/H/3136/001	79055.00.00	Hormosan Pharma Gmbh	Germany
Dorzolamide Mylan Generics	UK/H/1757/001/DC	040083014 \$ 040083026 \$ 040083038	Mylan S.P.A.	Italy
Dorzolamide Mylan	UK/H/1757/001/DC	NL 35468	Mylan S.A.S	France
Dorzolamide Hydrochloride	UK/H/3138/001	18391	Stada Arzneimittel Ag	Poland
Dorzolamide Hydrochloride	UK/H/3138/001	45318	Stada Arzneimittel Ag	Denmark
Dorzolamide Hydrochloride	UK/H/4305/001	80856.00.00	Stadapharm Gmbh	Germany
Dorzolamida Arena		6557/2014/01	Arena Group S.A	Romania
Dorzolamida Actavis	UK/H/3137/001	5348842	Actavis Group Ptc Ehf.	Portugal
Dorzolamida Kern Pharma		77.776	Kern Pharma, S.L.	Spain
Dorzolamida Pharmathen	UK/H/1252/001	5324116 \$ 5324124 \$ 5324132	Pharmathen International S.A.	Portugal
Dorzolamide Actavis	UK/H/3137/001	11-0010	Actavis Group Ptc Ehf.	Latvia
Dorzolamide Actavis	UK/H/3137/001	727311	Actavis Group Ptc Ehf.	Estonia
Dorzolamide Actavis	UK/H/3137/001	PA 1380/82/1	Actavis Group Ptc Ehf.	Ireland
Dorzolamide Actavis	UK/H/3137/001	RVG 105562	Actavis Group Ptc Ehf.	Netherlands
Dorzolamide Actavis	UK/H/3137/001	LT/1/10/2335/001-003	Actavis Group Ptc Ehf.	Lithuania
Dorzolamide	UK/H/3137/001	PL 30306/0251	Actavis Group Ptc Ehf.	United Kingdom
Dorzolamide	UK/H/5300/001/DC	PA1859/001/001	Blumont Pharma Ltd	Ireland

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Dorzolamide	UK/H/5300/001/DC	PL31103/0019	Blumont Pharma Ltd	United Kingdom
Dorzolamide Hydrochloride	UK/H/3138/001	RVG 105443	Centrafarm B.V.	Netherlands
Dorzolamide Hydrochloride	UK/H/3138/001	NL38146	Eg Labo - Laboratoires Eurogenerics	France
Dorzolamida Mylan	UK/H/1757/001/DC	5323928 \$ 5323936 \$ 5323944	Mylan Lda	Portugal
Dorzolamide Mylan	UK/H/1757/001/DC	RVG 101854	Mylan B.V.	Netherlands
Dorzolamide		PL25258/0107	Glenmark Pharmaceuticals Europe Limited	United Kingdom
Dorzolamide	IT/H/0252/001/DC	PL 18956/0017	Medicom Healthcare Ltd	United Kingdom
Dorzolamid Mylan	UK/H/1757/001/DC	42778	Mylan Ab	Denmark
Dorzolamide Mylan	UK/H/1757/001/DC	PA 405/052/001	McDermott Laboratories Limited, trading as Gerard Laboratories	Ireland
Dorzolamide		PL 17277/0345	Pharmathen S.A.	United Kingdom
Dorzolamide	UK/H/1252/001	PL 31225/0005	Pharmathen International S.A.	United Kingdom
Dorzolamide	UK/H/3136/001	PL 17277/0128	Pharmathen S.A.	United Kingdom
Dorzolamide Portfarma	UK/H/3136/001	11-0011	Portfarma Ehf	Latvia
Dorzolamide Portfarma	UK/H/3136/01/DC	IS/1/10/016/01	Portfarma Ehf	Iceland
Dorzolamide Hydrochloride	UK/H/4305/001	PL 11204/0276	Stada Arzneimittel Ag	United Kingdom
Dorzolamide	IT/H/0252/001/DC	AIC 039967017 \$ AIC 039967029 \$ AIC 039967031	Tubilux Pharma S.P.A.	Italy
Dorzolamid	UK/H/3591/001	80900.00.00	Fdc Pharma	Germany
Dorzolamid	UK/H/3591/001	75621	Fdc Pharma	Spain
Dorzolamide	UK/H/3591/001	PL 35638 /0006	Fdc Pharma	United Kingdom
Dorzostill	DK/H/1534/001	039620012 \$ 039620024	Bruschettini S.R.L	Italy
Dorzostill	DK/H/1534/001	43562	Bruschettini S.R.L	Denmark
Dorzostill	DK/H/1534/001	RVG 109493	Bruschettini S.R.L	Netherlands
Dorzostill	DK/H/1534/001/DC	039620036	Bruschettini S.R.L	Italy
Dorzostill	DK/H/1534/001/DC	17041	Bruschettini S.R.L	Poland
Dorzostill	DK/H/1534/001/DC	2185/2009/01	Bruschettini S.R.L	Romania

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Dozopres	UK/H/3136/001	OGYI-T-21634/01 \$ OGYI-T-21634/02 \$ OGYI-T-21634/03	Pharmaswiss česká Republika S.R.O.	Hungary
Dozotens	UK/H/4305/001	64/0928/10-S	Pharmaswiss česká Republika S.R.O.	Slovakia
Oftidor	CZ/H/0582/001	17951	Pharmaswiss česká Republika S.R.O.	Poland
Oftidor	CZ/H/0582/001	64/1054/10-C	Pharmaswiss česká Republika S.R.O.	Czech Republic
Oftidor	DE/H/1510/001	11-0014	Pharmaswiss česká Republika S.R.O.	Latvia
Oftidor	DE/H/1510/001	LT/1/11/2457/001 \$ LT/1/11/2457/002 \$ LT/1/11/2457/003	Pharmaswiss česká Republika S.R.O.	Lithuania
Oftidor 20 mg/mL kapi za oko, otopina		UP/I-530-09/12-01/189	Pharmaswiss česká Republika S.R.O.	Croatia
Dorzolamide Hydrochloride	UK/H/3138/001	PL 11204/0275	Stada Arzneimittel Ag	United Kingdom
Rozdol	AT/H/0546/001	17698	Sun-Farm Sp. Z.O.O.	Poland
Trusopt	FR/H/0070/001	1- 21324	Merck Sharp & Dohme Ges.M.B.H.	Austria
Trusopt	FR/H/0070/001	BE208546	Santen Oy	Belgium
Trusopt Unit Dose	FR/H/0070/002	BE285336	Santen Oy	Belgium
трусонт		20020978	Merck Sharp & Dohme Bulgaria Eood	Bulgaria
Trusopt		UP/I- 530-09/13-02/436	Santen Oy	Croatia
Trusopt		64/567/97-C	Merck Sharp & Dohme Bv	Czech Republic
Trusopt	FR/H/0070/002	64/417/05-C	Merck Sharp & Dohme Bv	Czech Republic
Trusopt	FR/H/0070/002	15910	Santen Oy	Denmark
Trusopt Ukonserveret	FR/H/0070/002	38051	Santen Oy	Denmark
Trusopt		155696	Merck Sharp & Dohme Ou	Estonia
Trusopt	FR/H/070/001	11787	Santen Oy	Finland
Trusopt	FR/H/0070/001	34009 338 513 0 9	Msd France	France
Trusopt	FR/H/0070/002	34009 366 139 2 8 \$ 34009 366 140 0 0 \$ 34009 370 616 6 7	Msd France	France

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Trusopt	FR/H/0070/001	32120.00.00	Santen Oy	Germany
Trusopt-S	FR/H/0070/002	63083.00.00	Santen Oy	Germany
Trusopt 20 Mg/MI οφθαλμικές σταγόνες	FR/H/0070/001	108326/14/15-01-2015	Vianex S.A.	Greece
Trusopt Pf " χωρίς συντηρητικό" 20mg/MI οφθαλμικές σταγόνες διάλυμα, σταγονόμετρα μίας δόσης	FR/H/0070/002	92284/28-12-12	Vianex S.A.	Greece
Trusopt Ocumeter Plus		OGYI-T-7670/01	Santen Oy	Hungary
Trusopt		940013 (IS)	Merck Sharp & Dohme Bv	Iceland
Trusopt		990053 (IS)	Merck Sharp & Dohme Bv	Iceland
Trusopt	FR/H/0070/001	PA0879/004/001	Santen Oy	Ireland
Trusopt Preservative-Free	FR/H/0070/002	PA0879/004/002	Santen Oy	Ireland
Trusopt	FR/H/070/001	031848017	Santen Oy	Italy
Trusopt		98 - 0168	Merck Sharp & Dohme Latvija Sia	Latvia
Trusopt		LT/1/96/1021/001	Merck Sharp & Dohme, Uab	Lithuania
Trusopt Unit Dose	FR/H/0070/002	2010090877	Santen Oy	Luxembourg
Trusopt	FR/H/0070/001	RVG 17618	Merck Sharp & Dohme Bv	Netherlands
Trusopt	FR/H/0070/002	RVG 32633	Merck Sharp & Dohme Bv	Netherlands
Trusopt		06-3929	Santen Oy	Norway
Trusopt		8172	Santen Oy	Norway
Trusopt		R/6613	Santen Oy	Poland
Trusopt	FR/H/0070/001	2303584 \$ 3085982 \$ 3086089	Santen Oy	Portugal
Trusopt	FR/H/0070/002	5587985 \$ 5588082 \$ 5588181	Santen Oy	Portugal
Trusopt		7216/2014/01	Santen Oy	Romania
Trusopt		64/0905/96-S	Merck Sharp & Dohme Bv	Slovakia
Trusopt	FR/H/0070/001	60.651	Santen Oy	Spain
Trusopt	FR/H/070/001	12208	Santen Oy	Sweden
Trusopt	FR/H/070/002	22553	Santen Oy	Sweden
Trusopt	FR/H/0070/001	PL 16058/0014	Santen Oy	United Kingdom

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Zoliop	UK/H/5300/001/DC	042570010 \$ 042570022 \$ 042570034	Farmigea Spa	Italy
Trusopt Preservative-Free	FR/H/0070/002	PL 16058/0013	Santen Oy	United Kingdom
Dorzolamide Actavis	UK/H/3137/001	040609/M	Actavis Group Ptc Ehf.	Italy
Dorzolamide FDC Pharma		419 872-0 (34009 419 872 0 5)	Fdc Pharma	France
Dorzolamide FDC Pharma		41558014	Fdc Pharma	Italy
Dorzolamide Generics [uk]	UK/H/1757/001/DC	PL 04569/0911	Generics [uk] Limited	United Kingdom
Dorzolamida Aristo		72752	Aristo Pharma Iberia	Spain
Dorzolamide Doc Generici		040189019	Doc Generici Srl	Italy
Dorzolamide Doc Generici		040189021	Doc Generici Srl	Italy
Dorzolamide Doc Generici		040189033	Doc Generici Srl	Italy
Dorzolamide ELVIM	UK/H/3136/001	724810	SIA ELVIM	Estonia
Galax	13/H/0076/001	5581723 \$ 5581731 \$ 5581749	Gide Farma - Produtos Farmacêuticos, Lda.	Portugal
Dorzolamid Mylan	UK/H/1757/001/DC	26615	Mylan Ab	Sweden
Dorzolamide Generics	UK/H/1757/001/DC	2114/14-01-2011	Generics [uk] Limited	Greece