



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 March 2018
EMA/154236/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ketotifen (ophthalmic formulations)

Procedure no.: PSUSA/00001812/201706



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
Agidot 0,125 mg/0,5 ml, col 71 rio, solu 777Jo	not available	5570361	GIDE FARMA - PRODUTOS FARMACÊUTICOS, LDA	PT
Agidot 0,125 mg/0,5 ml, col 71 rio, solu 777Jo	not available	5570346	GIDE FARMA - PRODUTOS FARMACÊUTICOS, LDA	PT
Agidot 0,125 mg/0,5 ml, col 71 rio, solu 777Jo	not available	5570353	GIDE FARMA - PRODUTOS FARMACÊUTICOS, LDA	PT
Agidot 0,125 mg/0,5 ml, col 71 rio, solu 777Jo	not available	5570379	GIDE FARMA - PRODUTOS FARMACÊUTICOS, LDA	PT
Agidot 0,125 mg/0,5 ml, col 71 rio, solu 777Jo	not available	5570403	GIDE FARMA - PRODUTOS FARMACÊUTICOS, LDA	PT
Agidot 0,125 mg/0,5 ml, col 71 rio, solu 777Jo	not available	5570411	GIDE FARMA - PRODUTOS FARMACÊUTICOS, LDA	PT
Allergo-Vision sine 0,25 mg/ml Augentropfen im Einzeldosisbehältnis	NL/H/2430/001	86124.00.00	OMNIVISION GMBH	DE
Altriabak 0,25 mg/ml, collyre en solution	FR/H/0411/001	BE374866	LABORATOIRES THEA	BE
Altriabak 0,25 mg/ml, collyre en solution	FR/H/0411/001	1536/10110003	LABORATOIRES THEA	LU
Altriabak 0,25 mg/ml, oogdruppels, oplossing	FR/H/0411/001	BE374866	LABORATOIRES THEA	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
Altriabak 0,25 mg/ml, oogdruppels, oplossing	FR/H/0411/001	RVG 105250	LABORATOIRES THEA	NL
Bentifen 0,25 mg/ml colirio en solución	SE/H/0226/001	63.618	LABORATOIRES THEA	ES
Bentifen 0,25 mg/ml collirio, soluzione	SE/H/0226/001	035591066	NOVARTIS FARMA S.P.A.	IT
Bentifen 0,25 mg/ml collirio, soluzione in contenitori monodose	SE/H/0226/002	035591027	NOVARTIS FARMA S.P.A.	IT
Bentifen 0,25 mg/ml collirio, soluzione in contenitori monodose	SE/H/0226/002	035591015	NOVARTIS FARMA S.P.A.	IT
Bentifen 0,25 mg/ml collirio, soluzione in contenitori monodose	SE/H/0226/002	035591039	NOVARTIS FARMA S.P.A.	IT
Bentifen 0,25 mg/ml collirio, soluzione in contenitori monodose	SE/H/0226/002	035591041	NOVARTIS FARMA S.P.A.	IT
Bentifen 0,25 mg/ml collirio, soluzione in contenitori monodose	SE/H/0226/002	035591054	NOVARTIS FARMA S.P.A.	IT
BENTIFEN 0,25 mg/ml, colírio, solução	SE/H/0226/001	3520780	LABORATOIRES THEA	PT

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
BENTIFEN 0,25 mg/ml, colírio, solução em unidoses.	SE/H/0226/002	3520889	LABORATOIRES THEA	PT
BENTIFEN 0,25 mg/ml, colírio, solução em unidoses.	SE/H/0226/002	3520988	LABORATOIRES THEA	PT
BENTIFEN 0,25 mg/ml, colírio, solução em unidoses.	SE/H/0226/002	3521085	LABORATOIRES THEA	PT
BENTIFEN 0,25 mg/ml, colírio, solução em unidoses.	SE/H/0226/002	3521184	LABORATOIRES THEA	PT
BENTIFEN 0,25 mg/ml, colírio, solução em unidoses.	SE/H/0226/002	3521283	LABORATOIRES THEA	PT
Bentifen 0.25 mg/ml, eye drops, solution in single-dose containers.	SE/H/0226/002	16252	LABORATOIRES THEA	SE
Bentifen 0.25 mg/ml, eye drops, solution.	SE/H/0226/001	16251	LABORATOIRES THEA	SE
BRUNISTILL 250 microgrammi/ml collirio, soluzione	not available	037448026	BRUSCHETTINI S.R.L	IT
EUSTAMYL 50 mg/ml collirio, soluzione	not available	039436011	NICOX FARMA S.R.L.	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
EUSTAMYL 50 mg/ml collirio, soluzione	not available	039436023	NICOX FARMA S.R.L.	IT
Ketofall 0.25 mg/ml eye drops, solution in single-dose container	NL/H/2430/001	PA 1815/002/001	PHARMA STULLN GMBH	IE
Ketofall 0.25 mg/ml eye drops, solution in single-dose container	NL/H/2430/001	PL 20905/0002	PHARMA STULLN GMBH	UK
KETOFTIL 0,5 mg/g gel oftalmico	not available	029278037	OFTAGEST SRL	IT
KETOFTIL 0,5 mg/ml collirio, soluzione	not available	029278013	OFTAGEST SRL	IT
KETOFTIL 0,5 mg/ml collirio, soluzione	not available	029278025	OFTAGEST SRL	IT
KETOFTIL 0.05% eye drops, solution	not available	029278013	FARMIGEA SPA	MT
KETOFTIL 0.05% ophthalmic gel	not available	029278037	FARMIGEA SPA	MT
Ketotifen Bipharma 0,25 mg/ml Augentropfen, Lösung in einem Einzeldosisbehältnis	HU/H/0383/001	BE485315	BIPHARMA B.V.	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
Ketotifen Bipharma 0,25 mg/ml egyadagos oldatos szemcsepp	HU/H/0383/001	OGYI-T-22954/01	BIPHARMA B.V.	HU
Ketotifen Bipharma 0,25 mg/ml egyadagos oldatos szemcsepp	HU/H/0383/001	OGYI-T-22954/02	BIPHARMA B.V.	HU
Ketotifen Bipharma 0,25 mg/ml egyadagos oldatos szemcsepp	HU/H/0383/001	OGYI-T-22954/03	BIPHARMA B.V.	HU
Ketotifen Bipharma 0,25 mg/ml egyadagos oldatos szemcsepp	HU/H/0383/001	OGYI-T-22954/04	BIPHARMA B.V.	HU
Ketotifen Bipharma 0,25 mg/ml egyadagos oldatos szemcsepp	HU/H/0383/001	OGYI-T-22954/05	BIPHARMA B.V.	HU
Ketotifen Bipharma 0,25 mg/ml voor éénmalig gebruik, oogdruppels, oplossing	HU/H/0383/001	BE485315	BIPHARMA B.V.	BE
Ketotifen Bipharma 0,25 mg/ml, collyre en solution, récipient unidose	HU/H/0383/001	BE485315	BIPHARMA B.V.	BE
Ketotifen Bipharma 0,25 mg/ml, oogdruppels, oplossing in een verpakking voor éénmalig gebruik	HU/H/0383/001	RVG 116667	BIPHARMA B.V.	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
Ketotifen Stulln 250 Mikrogramm/ml Augentropfen im Einzeldosisbehältnis	NL/H/2430/001	1-31688	PHARMA STULLN GMBH	AT
Ketotifen Stulln Unit Dose 0,25 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik	NL/H/2430/001	RVG 110580	PHARMA STULLN GMBH	NL
Ketotifen Stulln® UD 0,25 mg/ml Augentropfen in Einzeldosisbehältnissen Wirkstoff: Ketotifen	not available	79809.00.00	PHARMA STULLN GMBH	DE
KETOTIFENE THEA 0,25mg/ml, collyre en solution	FR/H/0412/001	492 504-8	LABORATOIRES THEA	FR
Ketotifeno FARMALIDER 0,25 mg/ml Colirio en solución	not available	73844	FARMALIDER, S.A.	ES
KETOVIS 0,25 mg/ml colirio en solución en envase unidos	NL/H/2430/001	77213	PHARMA STULLN GMBH	ES
Lidina 0,125 mg/0,5 ml, colírio, solução	not available	5379920	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Lidina 0,125 mg/0,5 ml, colírio, solução	not available	5379938	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT

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
Lidina 0,125 mg/0,5 ml, colírio, solução	not available	5379946	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Lidina 0,125 mg/0,5 ml, colírio, solução	not available	5381868	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Lidina 0,125 mg/0,5 ml, colírio, solução	not available	5381876	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Lidina 0,125 mg/0,5 ml, colírio, solução	not available	5381900	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
ZABAK 0,25 mg/ml picături oftalmice, soluție	FR/H/0411/001	9909/2017/01	LABORATOIRES THEA	RO
ZABAK 0,25 mg/ml, colírio, solução	FR/H/0411/001	5299326	LABORATOIRES THEA	PT
ZABAK 0,25 mg/ml, οφθαλμικές σταγόνες, διάλυμα	FR/H/0411/001	5915/26-1-2011	LABORATOIRES THEA	GR
ZABAK, 0,25 mg/ml, krople do oczu, roztwór	FR/H/0411/001	17772	LABORATOIRES THEA	PL
ZADITEN	not available	64/045/01-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
Zaditen 0,025% - Augentropfen	SE/H/0225/001	1-23998	LABORATOIRES THEA	AT
Zaditen 0,25 mg/ml , οφθαλμικές σταγόνες, διάλυμα.	not available	019261	LABORATOIRES THEA	CY
ZADITEN 0,25 mg/ml Augentropfen	SE/H/0225/001	2011071199	LABORATOIRES THEA	LU
Zaditen 0,25 mg/ml colirio en solución en envases unidosis	SE/H/0225/002	63.616	LABORATOIRES THEA	ES
Zaditen 0,25 mg/ml colirio en solución.	SE/H/0225/001	63.619	LABORATOIRES THEA	ES
Zaditen 0,25 mg/ml kapljice za oko, raztopina	not available	5363-I-1229/12	LABORATOIRES THEA	SI
Zaditen 0,25 mg/ml oldatos szemcsepp	not available	OGYI-T-7906/02	LABORATOIRES THEA	HU
Zaditen 0,25 mg/ml øyedråper, oppløsning i endosebeholdere	SE/H/0225/002	2000/04683	LABORATOIRES THEA	NO
ZADITEN 0,25 mg/ml picături oftalmice soluție	not available	8281/2006/01	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
ZADITEN 0,25 mg/ml picături oftalmice soluție, în recipient unidoza	not available	8280/2006/04	LABORATOIRES THEA	RO
ZADITEN 0,25 mg/ml picături oftalmice soluție, în recipient unidoza	not available	8280/2006/05	LABORATOIRES THEA	RO
ZADITEN 0,25 mg/ml picături oftalmice soluție, în recipient unidoză	not available	8280/2006/01	LABORATOIRES THEA	RO
ZADITEN 0,25 mg/ml picături oftalmice soluție, în recipient unidoză	not available	8280/2006/02	LABORATOIRES THEA	RO
ZADITEN 0,25 mg/ml picături oftalmice soluție, în recipient unidoză	not available	8280/2006/03	LABORATOIRES THEA	RO
Zaditen 0,25 mg/ml silmätipat, liuos	SE/H/0225/001	15990	LABORATOIRES THEA	FI
Zaditen 0,25 mg/ml silmätipat, liuos kerta-annospakkauksessa	SE/H/0225/002	15989	LABORATOIRES THEA	FI
Zaditen 0,25 mg/ml, augndropar, lausn	SE/H/0225/001	IS/1/00/022/01	LABORATOIRES THEA	IS
Zaditen 0,25 mg/ml, augndropar, lausn í stakskammtaílátum.	SE/H/0225/002	IS/1/00/022/02	LABORATOIRES THEA	IS

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
ZADITEN 0,25 mg/ml, colírio, solução	SE/H/0225/001	3520186	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em unidoses	SE/H/0225/002	3520285	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em unidoses	SE/H/0225/002	3520384	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em unidoses	SE/H/0225/002	3520483	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em unidoses	SE/H/0225/002	3520582	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em unidoses	SE/H/0225/002	3520681	LABORATOIRES THEA	PT
Zaditen 0,25 mg/ml, očná roztoková instilácia	not available	64/0268/03-S	LABORATOIRES THEA	SK
Zaditen 0,25 mg/ml, ögondroppar, lösning	SE/H/0225/001	15588	LABORATOIRES THEA	SE
Zaditen 0,25 mg/ml, ögondroppar, lösning endosbehållare	SE/H/0225/002	15589	LABORATOIRES THEA	SE

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
Zaditen 0,25 mg/ml, oogdruppels, oplossing	SE/H/0225/001	RVG 25726	LABORATOIRES THEA	NL
Zaditen 0,50 mg/ml oldatos szemcsepp	not available	OGYI-T-7906/01	LABORATOIRES THEA	HU
Zaditen 0.25 mg/ml, eye drops, solution	SE/H/0225/001	PL 20162/0019	LABORATOIRES THEA	UK
Zaditen 0.25 mg/ml, eye drops, solution	SE/H/0225/001	PA 1107/010/001	LABORATOIRES THEA	IE
Zaditen konservierungsmittelfrei 0,025% - Augentropfen in Einzeldosisbehältnissen	SE/H/0225/002	1-23999	LABORATOIRES THEA	AT
ZADITEN OFTABAK 0,25 mg/ml collirio soluzione	FR/H/0411/001	040504019	LABORATOIRES THEA	IT
ZADITEN Ophtha ABAK 0,25 mg/ml Augentropfen	FR/H/0411/001	1-29510	LABORATOIRES THEA	AT
Zaditen SDU 0,025% Oční kapky, roztok v jednodávkových obalech	SE/H/0225/002	64/212/05-C	LABORATOIRES THEA	CZ
Zaditen SDU 0,25 mg/ml kapljice za oko, raztopina v enodmernih vsebnikih	not available	5363-I-1230/12	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
ZADITEN UNIDOSE 0,25 mg/ml Augentropfen Lösung in Einzeldosisbehältnissen	SE/H/0225/002	2011071200	LABORATOIRES THEA	LU
Zaditen Unidose 0,25 mg/ml, oogdruppels, oplossing in verpakking voor eenmalig gebruik	SE/H/0225/002	RVG 25727	LABORATOIRES THEA	NL
Zaditen, 0,25 mg/ml øyedråper, oppløsning	SE/H/0225/001	00-4682	LABORATOIRES THEA	NO
Zaditen, 0,25 mg/ml, krople do oczu, roztwór	not available	10767	LABORATOIRES THEA	PL
Zaditen, øjendråber, opløsning	SE/H/225/001	31701	LABORATOIRES THEA	DK
Zaditen, øjendråber, opløsning, enkeltdosisbeholder	SE/H/225/002	31702	LABORATOIRES THEA	DK
ZADITEN®	not available	MA088/04601	LABORATOIRES THEA	MT
ZADITEN® ophtha 0,25 mg/ml Augentropfen	SE/H/0225/001	50256.00.00	LABORATOIRES THEA	DE
ZADITEN® ophtha sine 0,25 mg/ml Augentropfen Lösung in	SE/H/0225/002	50257.00.00	LABORATOIRES THEA	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
Einzel dosisbehältnissen				
Zaditor 0,25 mg/ml, νθζαικηθέο ζηαγόλεο, δηάικα.ζε πεξηέθηεο κηαο δόζεο	SE/H/0225/002	14519/25-2-2013	LABORATOIRES THEA	GR
Zaditor 0.25 mg/ml , νθζαικηθέο ζηαγόλεο, δηάικα.	SE/H/0225/001	84841/12/25-2-2013	LABORATOIRES THEA	GR
Zalerg	FR/H/0411/001	45146	LABORATOIRES THEA	DK
ZALERG 0,25 mg/ml, colirio en solución	FR/H/0411/001	73518	LABORATOIRES THEA	ES
ZALERG 0,25 mg/ml, collyre en solution	FR/H/0411/001	492503-1	LABORATOIRES THEA	FR
ZALERG 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	300 043-3	LABORATOIRES THEA	FR
ZALERG 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	356 075-1	LABORATOIRES THEA	FR
ZALERG 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	356 076-8	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
ZALERG 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	356 077-4	LABORATOIRES THEA	FR
ZALERG 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	356 165-0	LABORATOIRES THEA	FR
ZALERG 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	356 166-7	LABORATOIRES THEA	FR
ZALERGONIUM 0,25 mg/ml, collyre en solution	SE/H/0225/001	356 074-5	LABORATOIRES THEA	FR
ЗАБАК 0,25 mg/ml капки за очи, разтвор	FR/H/0411/001/DC	20120164	LABORATOIRES THEA	BG