



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 February 2023
EMA/100177/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ketotifen (ophthalmic formulations)

Procedure no.: PSUSA/00001812/202206



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
Allergo-Vision sine 0,25 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	NL/H/2430/001/DC	86124.00.00	OMNIVISION GMBH	DE
Altriabak 0,25 mg/ml, Augentropfen	FR/H/0411/001	BE374866	LABORATOIRES THEA	BE
Altriabak 0,25 mg/ml, Augentropfen	FR/H/0411/001	2010110003	LABORATOIRES THEA	LU
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	2010110003	LABORATOIRES THEA	LU
Altriabak 0,25 mg/ml, oogdruppels, oplossing	FR/H/0411/001	BE374866	LABORATOIRES THEA	BE
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, eye drops, solution.	SE/H/0226/001	16251	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
Bentifen, 0,25 mg/ml, Ögondroppar, lösning, endosbehållare	SE/H/0226/002	16252	LABORATOIRES THEA	SE
BRUNISTILL 250 microgrammi/ml collirio, soluzione	not available	037448026	BRUSCHETTINI S.R.L	IT
EUSTAMYL 0,5 mg/ml collirio, soluzione	not available	039436011	VISUFARMA SPA	IT
EUSTAMYL 0,5 mg/ml collirio, soluzione	not available	039436023	VISUFARMA SPA	IT
Ketazed 0,25 mg/ml Augentropfen, Lösung.	NL/H/4814/001	7007924.00.00	HORUS PHARMA	DE
Ketazed 0,25 mg/ml collyre en solution.	NL/H/4814/001	BE581857	HORUS PHARMA	BE
Ketazed 0,25 mg/ml collyre en solution.	NL/H/4814/001	2021020015	HORUS PHARMA	LU
Ketazed 0,25 mg/ml ögondroppar, lösning	NL/H/4814/001	40461	HORUS PHARMA	FI
Ketazed 0,25 mg/ml ögondroppar, lösning	NL/H/4814/01	62941	HORUS PHARMA	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
Ketazed 0,25 mg/ml øyedråper, oppløsning	NL/H/4814/001	22-14562	HORUS PHARMA	NO
Ketazed 0,25 mg/ml picături oftalmice, soluție	NL/H/4814/001	14559/2022/01	HORUS PHARMA	RO
Ketazed 0,25 mg/ml silmätipat, liuos	NL/H/4814/001	40461	HORUS PHARMA	FI
Ketazed 0,25 mg/ml, Augentropfen, Lösung	NL/H/4814/001	BE581857	HORUS PHARMA	BE
Ketazed 0,25 mg/ml, Augentropfen, Lösung	NL/H/4814/001	2021020015	HORUS PHARMA	LU
KETAZED 0,25 mg/mL, collyre en solution	NL/H/4814/001	34009 302 196 7 6	HORUS PHARMA	FR
Ketazed 0,25 mg/ml, oogdruppels, oplossing	NL/H/4814/001	RVG 124606	HORUS PHARMA	NL
Ketazed 0,25 mg/ml, oogdruppels, oplossing.	NL/H/4814/001	BE581857	HORUS PHARMA	BE
Ketazed, øjendråber, opløsning	NL/H/4814/001	67253	HORUS PHARMA	DK

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
Ketirix 0,25 mg/ml collirio, soluzione	not available	048199018	GENETIC SPA	IT
Ketirix 0,25 mg/ml collirio, soluzione in contenitore monodose	not available	048199020	GENETIC SPA	IT
Ketisal 0,25 mg/ml colirio en solución.	NL/H/4814/001	85755	HORUS PHARMA	ES
KETOBRILL 0,25 mg/ml colirio en solución en envase unidosis	NL/H/2430/001	77213	PHARMA STULLN GMBH	ES
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	XI
KETOFTIL 0,5 mg/g gel oftalmico	not available	029278037	POLIFARMA S.P.A	IT
KETOFTIL 0,5 mg/ml collirio, soluzione	not available	029278013	POLIFARMA S.P.A	IT
KETOFTIL 0,5 mg/ml collirio,soluzione	not available	029278025	POLIFARMA S.P.A	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
Ketotifen Penta Arzneimittel 0,25 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	NL/H/4462/001	2202817.00.00	PENTA ARZNEIMITTEL GMBH	DE
Ketotifen Stulln 0,25 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik	NL/H/4462/001	RVG 123621	PHARMA STULLN GMBH	NL
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	not available	79809.00.00	PHARMA STULLN GMBH	DE
KETOTIFENE THEA 0,25 mg/ml, collyre en solution	FR/H/0412/001	34009 492 504 8 6	LABORATOIRES THEA	FR
Ketotifeno Codramol 0,25 mg/ml colirio en solución en envase unidosis	not available	82296	NUTRA ESSENTIAL OTC, S.L.	ES
Ketotifeno Dermogen 0,25 mg/ml colirio en solución en envase unidosis	not available	82297	NUTRA ESSENTIAL OTC, S.L.	ES

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
Ketotifeno FARMALIDER 0,25 mg/ml Colirio en solución	not available	73844	FARMALIDER, S.A.	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	5379946	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
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
Ocutifex 0,25 mg/ml silmätipat, liuos, kerta- annospakkaus	NL/H/4462/001	38693	PHARMA STULLN GMBH	FI
Paveket 0,25 mg/ml collirio, soluzione	not available	048205013	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
Paveket 0,25 mg/ml collirio, soluzione in contenitore monodose	not available	048205025	GENETIC SPA	IT
Reluviz 0,25 mg/ml collirio, soluzione	not available	048203018	GENETIC SPA	IT
Reluviz 0,25 mg/ml collirio, soluzione in contenitore monodose	not available	048203020	GENETIC SPA	IT
UTENOS 0.25 mg/ml οφθαλμικές σταγόνες, διάλυμα σε περιέκτες μίας δόσης.	NL/H/4462/001	31819/29-04-2021	PHARMA STULLN GMBH	GR
Visiofen 0,25 mg/ml collirio, soluzione in contenitore monodose	NL/H/4462/001/DC	049406010	OMNIVISION ITALIA S.R.L.	IT
Visiofen 0,25 mg/ml collirio, soluzione in contenitore monodose	NL/H/4462/001/DC	049406022	OMNIVISION ITALIA S.R.L.	IT
Visiofen 0,25 mg/ml collirio, soluzione in contenitore monodose	NL/H/4462/001/DC	049406034	OMNIVISION ITALIA S.R.L.	IT
Visiofen 0,25 mg/ml collirio, soluzione in contenitore monodose	NL/H/4462/001/DC	049406046	OMNIVISION ITALIA S.R.L.	IT
Visiofen 0,25 mg/ml collirio, soluzione in contenitore monodose	NL/H/4462/001/DC	049406059	OMNIVISION ITALIA 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
Visiofen 0,25 mg/ml collirio, soluzione in contenitore monodose	NL/H/4462/001/DC	049406061	OMNIVISION ITALIA S.R.L.	IT
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	117104/17/06-09-2018	LABORATOIRES THEA	GR
ZABAK, 0,25 mg/ml, krople do oczu, roztwór	FR/H/0411/001	17772	LABORATOIRES THEA	PL
Zaditen 0,025% - Augentropfen	SE/H/0225/001	1-23998	LABORATOIRES THEA	AT
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	H/03/01691/001	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 0,25 mg/ml ögondroppar, lösning	SE/H/0225/001	15990	LABORATOIRES THEA	FI
Zaditen 0,25 mg/ml ögondroppar, lösning i endosbehållare	SE/H/0225/002	15989	LABORATOIRES THEA	FI
Zaditen 0,25 mg/ml ögondroppar, lösning.	SE/H/0225/001	15588	LABORATOIRES THEA	SE
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	00-4683	LABORATOIRES THEA	NO
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 í stakskammtaílátum.	SE/H/0225/002	IS/1/00/022/02	LABORATOIRES THEA	IS
Zaditen 0,25 mg/ml, augndropar, lausn.	SE/H/0225/001	IS/1/00/022/01	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 recipiente unidose	SE/H/0225/002	3520285	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em recipiente unidose	SE/H/0225/002	3520384	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em recipiente unidose	SE/H/0225/002	3520483	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em recipiente unidose	SE/H/0225/002	3520582	LABORATOIRES THEA	PT
ZADITEN 0,25 mg/ml, colírio, solução em recipiente unidose	SE/H/0225/002	3520681	LABORATOIRES THEA	PT
Zaditen 0,25 mg/ml, collyre en solution	SE/H/0225/001	2011071199	LABORATOIRES THEA	LU
Zaditen 0,25 mg/ml, ocná roztoková instilácia	not available	64/0268/03-S	LABORATOIRES THEA	SK
Zaditen 0,25 mg/ml, ögondroppar, lösning i 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 0,25 mg/ml, οφθαλμικές σταγόνες, διάλυμα.	not available	19261	LABORATOIRES THEA	CY
Zaditen 0.25 mg/ml, eye drops, solution.	SE/H/0225/001	PL 20162/0019	LABORATOIRES THEA	XI
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	H/03/01691/002	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 SDU 0,25 mg/ml kapljice za oko, raztopina v enoodmernih vsebnikih	not available	H/03/01691/003	LABORATOIRES THEA	SI
Zaditen Unidose 0,25 mg/ml, collyre en solution en récipient unidose	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, øjendråber, opløsning	SE/H/0225/001	31701	LABORATOIRES THEA	DK
Zaditen, øjendråber, opløsning, enkeltdosisbeholder	SE/H/0225/002	31702	LABORATOIRES THEA	DK
ZADITEN® ophtha 0,25 mg/ml Augentropfen Wirkstoff: Ketotifenfumarat	SE/H/0225/001	50256.00.00	LABORATOIRES THEA	DE
ZADITEN® ophtha sine 0,25 mg/ml Augentropfen Lösung in Einzeldosisbehältnissen Wirkstoff: Ketotifenfumarat	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
Zaditor 0,25 mg/ml, οφθαλμικές σταγόνες, διάλυμα σε περιέκτες μίας δόσης	SE/H/0225/002	14519/25-2-2013	LABORATOIRES THEA	GR
Zaditor 0,25 mg/ml, οφθαλμικές σταγόνες, διάλυμα.	SE/H/0225/001	84841/12/25-2-2013	LABORATOIRES THEA	GR
ZAGRAPA 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	340009 300 043 3 3	LABORATOIRES THEA	FR
ZAGRAPA 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	340009 356 075 1 5	LABORATOIRES THEA	FR
ZAGRAPA 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	340009 356 076 8 3	LABORATOIRES THEA	FR
ZAGRAPA 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	340009 356 077 4 4	LABORATOIRES THEA	FR
ZAGRAPA 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	340009 356 165 0 0	LABORATOIRES THEA	FR
ZAGRAPA 0,25 mg/ml, collyre en solution en récipient unidose	SE/H/0225/002	340009 356 166 7 8	LABORATOIRES THEA	FR
ZALERG 0,25 mg/ml, collyre en solution	FR/H/0411/001	34009 492 503 1 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, øjendråber, opløsning	FR/H/0411/001	45146	LABORATOIRES THEA	DK
ZALERGONIUM 0,25 mg/ml, collyre en solution	SE/H/0225/001	34009 356 074 5 4	LABORATOIRES THEA	FR
ЗАБАК 0,25 mg/ml капки за очи, разтвор	FR/H/0411/001	20120164	LABORATOIRES THEA	BG