



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

8 July 2021  
EMA/392177/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: phenylephrine / tropicamide

Procedure no.: PSUSA/00010430/202011

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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An agency of the European Union



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Mydriaserit 0,28 mg / 5,4 mg, insert ophtalmique	FR/H/0273/001	BE310572	LABORATOIRES THEA	BE
Mydriaserit 0,28 mg / 5,4 mg, insert ophtalmique	FR/H/0273/001	2008040015	LABORATOIRES THEA	LU
Mydriaserit 0,28 mg / 5,4 mg, ooginsert	FR/H/0273/001	BE 310572	LABORATOIRES THEA	BE
Mydriaserit 0,28 mg/5,4 mg Augeninsert	FR/H/0273/001	1-27374	LABORATOIRES THEA	AT
Mydriaserit 0,28 mg/5,4 mg Augeninsert	FR/H/0273/001	65710.00.00	LABORATOIRES THEA	DE
Mydriaserit 0,28 mg/5,4 mg inserto oftalmico	FR/H/0273/001	037716014	LABORATOIRES THEA	IT
Mydriaserit 0,28 mg/5,4 mg inserto oftalmico	FR/H/0273/001	037716026	LABORATOIRES THEA	IT
Mydriaserit 0,28 mg/5,4 mg inserto oftalmico	FR/H/0273/001	037716038	LABORATOIRES THEA	IT
Mydriaserit 0,28 mg/5,4 mg inserto oftalmico	FR/H/0273/001	037716040	LABORATOIRES THEA	IT

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Mydriaserit 0,28 mg/5,4 mg inserto oftálmico	FR/H/0273/001	037716053	LABORATOIRES THEA	IT
Mydriaserit 0,28 mg/5,4 mg Inserto oftálmico	FR/H/0273/001	70710	LABORATOIRES THEA	ES
Mydriaserit 0,28 mg/5,4 mg ögonlamell	FR/H/0273/001	23485	LABORATOIRES THEA	SE
Mydriaserit 0,28 mg/5,4 mg silmälamelli	FR/H/0273/001	21979	LABORATOIRES THEA	FI
Mydriaserit 0.28 mg/5.4 mg ophthalmic insert	FR/H/0273/001	PL 20162/0011	LABORATOIRES THEA	XI
Mydriaserit 5.4 mg + 0.28 mg Inserto oftálmico	FR/H/0273/001	5893789	LABORATOIRES THEA	PT
Mydriaserit 5.4 mg + 0.28 mg Inserto oftálmico	FR/H/0273/001	5893888	LABORATOIRES THEA	PT
Mydriaserit 5.4 mg + 0.28 mg Inserto oftálmico	FR/H/0273/001	5893987	LABORATOIRES THEA	PT
Mydriaserit 5.4 mg + 0.28 mg Inserto oftálmico	FR/H/0273/001	5894084	LABORATOIRES THEA	PT

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Mydriaserit 5.4 mg + 0.28 mg Inserto oftálmico	FR/H/0273/001	5894183	LABORATOIRES THEA	PT
MYDRIASERT, insert ophtalmique	FR/H/0273/001	353 728-4	LABORATOIRES THEA	FR
MYDRIASERT, insert ophtalmique	FR/H/0273/001	353 578-2	LABORATOIRES THEA	FR
MYDRIASERT, insert ophtalmique	FR/H/0273/001	353 729-0	LABORATOIRES THEA	FR
MYDRIASERT, insert ophtalmique	FR/H/0273/001	353 579-9	LABORATOIRES THEA	FR
MYDRIASERT, insert ophtalmique	FR/H/0273/001	353 580-7	LABORATOIRES THEA	FR
Mydriaserit, øjenlanel	FR/H/0273/001	39059	LABORATOIRES THEA	DK
Mydriaserit, ooginsert 0,28 mg en 5,4 mg	FR/H/0273/001	RVG 33701	LABORATOIRES THEA	NL
VISUMIDRIATIC FENILEFRINA "100mg/ml + 5mg/ml Collirio, Soluzione"	not available	020698015	VISUFARMA SPA	IT