



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 January 2025  
EMA/28300/2025  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): loteprednol

Procedure No. PSUSA/00001913/202405



<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>
Lotemax 0,5 % akių lašai (suspensija)	IE/H/0765/001	LT/1/05/0388/001	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	LT
Lotemax 0,5 % akių lašai (suspensija)	IE/H/0765/001	LT/1/05/0388/002	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	LT
Lotemax 0,5 % akių lašai (suspensija)	IE/H/0765/001	LT/1/05/0388/003	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	LT
Lotemax 0,5 % kapljice za oko, suspenzija	IE/H/0765/001	H/06/00953/001	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	SI
Lotemax 0,5 % kapljice za oko, suspenzija	IE/H/0765/001	H/06/00953/002	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	SI
Lotemax 0,5 % kapljice za oko, suspenzija	IE/H/0765/001	H/06/00953/003	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	SI
Lotemax 0,5 %, očné suspenzné kvapky	IE/H/0765/001	64/0359/05 – S	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	SK
Lotemax 0,5% acu pilieni, suspensija	IE/H/0765/001	05-0532	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	LV
Lotemax 0,5% Augentropfensuspension	IE/H/0765/001	1-26328	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	AT
LOTEMAX 0,5% Collirio, Sospensione	IE/H/0765/001	036668022	BAUSCH & LOMB IOM S.P.A	IT
LOTEMAX 0,5% Collirio, Sospensione	IE/H/0765/001	036668034	BAUSCH & LOMB IOM S.P.A	IT
LOTEMAX 0,5% Collirio, Sospensione	IE/H/0765/001	036668010	BAUSCH & LOMB IOM S.P.A	IT
LOTEMAX 0,5% w/v Οφθαλμικές Σταγόνες, Εναιώρημα	IE/H/0765/001	58120/ 12-12-2016	OLYMPUS TRADING MEDICAL PRODUCTS I.K.E.	GR
LOTEMAX 0,5% οφθαλμικές σταγόνες, εναιώρημα	IE/H/0765/001	20230	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	CY
Lotemax 0,5%, 5 mg/ml, krople do oczu, zawiesina	IE/H/0765/001	12006	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	PL
Lotemax 0.5% w/v Eye Drops, Suspension	IE/H/0765/001	PA 1245/001/001	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	IE
Lotemax 0.5% w/v Eye Drops, Suspension	IE/H/0765/001	PL 56094/0002	BAUSCH + LOMB IRELAND LIMITED	XI

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Lotemax, 0,5% silmatilgad, suspension	IE/H/0765/001	492705	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	EE
Lotemax® 5 mg/ml Augentropfensuspension Loteprednoletabonat	IE/H/0765/001	59337.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
NOLOK 5 mg/ml collirio, sospensione	not available	049102015	ALFA INTES INDUSTRIA TERAPEUTICA SPLENDORE VIA FRATELLI	IT
NOLOK 5 mg/ml collirio, sospensione in contenitore monodose	not available	049102027	ALFA INTES INDUSTRIA TERAPEUTICA SPLENDORE VIA FRATELLI	IT