



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 March 2019
EMA/278257/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: opium

Procedure no.: PSUSA/00010670/201808

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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
Opium "NMI" orale dråber, opløsning	not available	16430	PHARMANOVIA A/S	DK
Dropizol 10 mg/ml dropar, lausn	DK/H/2691/001	IS/1/17/080/01	PHARMANOVIA A/S	IS
Dropizol 10 mg/ml oral drops, solution	DK/H/2691/001	PL 41284/0003	PHARMANOVIA A/S	UK
Dropizol 10 mg/ml orale dråber, opløsning	DK/H/2691/001	58376	PHARMANOVIA A/S	DK
Dropizol 10 mg/ml tipat, liuos	DK/H/2691/001	34485	PHARMANOVIA A/S	FI
Dropizol 10 mg/ml dråper, oppløsning	DK/H/2691/001	16-11321	PHARMANOVIA A/S	NO
Dropizol 10 mg/ml orala droppar, lösning	DK/H/2691/001	55287	PHARMANOVIA A/S	SE
Dropizol 10 mg/ml belsőleges oldatos cseppek	DK/H/2691/001	OGYI-T-23381/01	PHARMANOVIA A/S	HU
Dropizol 10 mg/ml belsőleges oldatos cseppek	DK/H/2691/001	OGYI-T-23381/02	PHARMANOVIA A/S	HU

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
Dropizol 10 mg/ml belsőleges oldatos cseppek	DK/H/2691/001	OGYI-T-23381/03	PHARMANOVIA A/S	HU
Dropizol 10mg/ml Oral Drops Solution	DK/H/2691/001	PA2245/001/001	PHARMANOVIA A/S	IE
Dropizol 10 mg/ml Tropfen zum Einnehmen, Lösung	DK/H/2691/001	138475	PHARMANOVIA A/S	AT
Dropizol 10 mg/ml Tropfen zum Einnehmen, Lösung	DK/H/2691/001	2201401.00.00	PHARMANOVIA A/S	DE
Dropizol 10 mg/ml druppels voor oraal gebruik, oplossing	DK/H/2691/001/E/001	RVG 122163	PHARMANOVIA A/S	NL
Dropizol 10 mg/ml picaturi orale, solutie	DK/H/2691/001/E001	10930/2018/01-02-03	PHARMANOVIA A/S	RO
Dropizol 10 mg/ml peroralne roztokove kvapky	DK/H/2691/001/E001	49/0251/18-S	PHARMANOVIA A/S	SK