



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 May 2022
EMA/254662/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: opium

Procedure no.: PSUSA/00010670/202109



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
DROPIZAL 10 mg/mL, solution buvable en gouttes	DK/H/2691/001	34009 301 953 6 9	PHARMANOVIA A/S	FR
DROPIZAL 10 mg/mL, solution buvable en gouttes	DK/H/2691/001	34009 301 953 8 3	PHARMANOVIA A/S	FR
DROPIZAL 10 mg/mL, solution buvable en gouttes	DK/H/2691/001	34009 301 953 9 0	PHARMANOVIA A/S	FR
DROPIZAL 10 mg/mL, solution buvable en gouttes	DK/H/2691/001	34009 301 954 0 6	PHARMANOVIA A/S	FR
DROPIZAL 10 mg/mL, solution buvable en gouttes	DK/H/2691/001	34009 301 954 1 3	PHARMANOVIA A/S	FR
DROPIZAL 10 mg/mL, solution buvable en gouttes	DK/H/2691/001	34009 301 954 2 0	PHARMANOVIA A/S	FR
Dropizale 10 mg/ml gotas orais, solução	DK/H/2691/001/E/001	5755400	PHARMANOVIA A/S	PT
Dropizale 10 mg/ml gotas orais, solução	DK/H/2691/001/E/001	5755418	PHARMANOVIA A/S	PT
Dropizale 10 mg/ml gotas orais, solução	DK/H/2691/001/E/001	5755426	PHARMANOVIA A/S	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
Dropizol 10 mg/ml belsőleges oldatos cseppek	DK/H/2691/001	OGYI-T-23381/04	PHARMANOVIA A/S	HU
Dropizol 10 mg/ml belsőleges oldatos cseppek	DK/H/2691/001	OGYI-T-23381/05	PHARMANOVIA A/S	HU
Dropizol 10 mg/ml belsőleges oldatos cseppek	DK/H/2691/001	OGYI-T-23381/06	PHARMANOVIA A/S	HU
Dropizol 10 mg/ml dråper, oppløsning	DK/H/2691/001	16-11321	PHARMANOVIA A/S	NO
Dropizol 10 mg/ml dropar, lausn.	DK/H/2691/001	IS/1/17/080/01	PHARMANOVIA A/S	IS
Dropizol 10 mg/ml druppels voor oraal gebruik, oplossing	DK/H/2691/001	RVG 122163	PHARMANOVIA A/S	NL
Dropizol 10 mg/ml oral drops, solution	DK/H/2691/001	PL 41284/0003	PHARMANOVIA A/S	XI
Dropizol 10 mg/ml orala droppar, lösning	DK/H/2691/001	55287	PHARMANOVIA A/S	SE
Dropizol 10 mg/ml peroralne roztokove kvapky	DK/H/2691/001	49/0251/18-S	PHARMANOVIA A/S	SK

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 perorální kapky, roztok	DK/H/2691/001	49/466/17-C	PHARMANOVIA A/S	CZ
Dropizol 10 mg/ml picături orale, soluție	DK/H/2691/001/E001	10930/2018/01	PHARMANOVIA A/S	RO
Dropizol 10 mg/ml picături orale, soluție	DK/H/2691/001	10930/2018/02	PHARMANOVIA A/S	RO
Dropizol 10 mg/ml picături orale, soluție	DK/H/2691/001	10930/2018/03	PHARMANOVIA A/S	RO
Dropizol 10 mg/ml solución oral en gotas	DK/H/2691/001	83323	PHARMANOVIA A/S	ES
Dropizol 10 mg/ml tipat, liuos	DK/H/2691/001	34485	PHARMANOVIA A/S	FI
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 Tropfen zum Einnehmen, Lösung	DK/H/2691/001	2019110240	PHARMANOVIA A/S	LU

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, solution buvable en gouttes	DK/H/2691/001	BE539662	PHARMANOVIA A/S	BE
Dropizol 10 mg/ml, solution buvable en gouttes	DK/H/2691/001	2019110240	PHARMANOVIA A/S	LU
Dropizol 10mg/ml Oral Drops Solution	DK/H/2691/001	PA2245/001/001	PHARMANOVIA A/S	IE
Dropizol, orale dråber, opløsning	DK/H/2691/001	58376	PHARMANOVIA A/S	DK
Dropizole 10 mg/ml druppels voor oraal gebruik, oplossing	DK/H/2691/001	BE539662	PHARMANOVIA A/S	BE
Dropizole 10 mg/ml gocce orali, soluzione	DK/H/2691/001	046396014	PHARMANOVIA A/S	PT
Dropizole 10 mg/ml gocce orali, soluzione	DK/H/2691/001	046396026	PHARMANOVIA A/S	PT
Dropizole 10 mg/ml gocce orali, soluzione	DK/H/2691/001	046396038	PHARMANOVIA A/S	PT
Dropizole 10 mg/ml Tropfen zum Einnehmen, Lösung	DK/H/2691/001	BE539662	PHARMANOVIA A/S	BE