1 October 2020
EMA/PRAC/535721/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: mannitol (all indications apart from cystic fibrosis)

Procedure no.: PSUSA/00010005/202002

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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
Aridol inhalaatiojauhe, kapseli, kova	SE/H/0711/001	22940	PHARMAXIS EUROPE LIMITED	FI
Aridol inhalasjonspulver, hard kapsel	SE/H/0711/001	06-4599	PHARMAXIS EUROPE LIMITED	NO
Aridol inhalationspulver, hård kapsel.	SE/H/0711/001	22708	PHARMAXIS EUROPE LIMITED	SE
Aridol inhalationspulver, hårda kapslar	SE/H/0711/001	22940	PHARMAXIS EUROPE LIMITED	FI
Aridol Pulver zur Inhalation	SE/H/0711/001	68119.00.00	PHARMAXIS EUROPE LIMITED	DE
Isotol – 20% soluzione per infusione	not available	020294029	DIACO BIOFARMACEUTICI S.R.L.	IT
Isotol – 20% soluzione per infusione	not available	020294017	DIACO BIOFARMACEUTICI S.R.L.	IT
MANNITOL LAVOISIER 20 POUR CENT, solution pour perfusion	not available	3400934487415	LABORATOIRES CHAIX ET DU MARAIS	FR
Osmohale inhalation powder, hard capsule	SE/H/0711/001	PA 22655/001/001	PHARMAXIS EUROPE LIMITED	IE

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
Osmohale inhalation powder, hard capsule	SE/H/0711/001	PL 50608/0001	PHARMAXIS EUROPE LIMITED	UK
Osmohale, inhalatiepoeder in harde capsules	SE/H/0711/001	RVG 34641	PHARMAXIS EUROPE LIMITED	NL
Osmohale, inhalationspulver, hård kapsel	SE/H/0711/001	40400	PHARMAXIS EUROPE LIMITED	DK
Osmohale, polvo para inhalación (cápsulas duras)	SE/H/0711/001	69945	PHARMAXIS EUROPE LIMITED	ES