



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2017
EMA/716838/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure No.: PSUSA/00010005/201702



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 PHARMACEUTICALS LIMITED	FI
Aridol inhalasjonspulver, hard kapsel	SE/H/0711/001/01	06-4599	PHARMAXIS PHARMACEUTICALS LIMITED	NO
Aridol inhalationspulver, hård kapsel	SE/H/0711/001	22708	PHARMAXIS PHARMACEUTICALS LIMITED	SE
Aridol inhalationspulver, hårda kapslar	SE/H/0711/001	22940	PHARMAXIS PHARMACEUTICALS LIMITED	FI
Aridol Pulver zur Inhalation	SE/H/0711/001	68119.00.00	PHARMAXIS PHARMACEUTICALS 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	VNL6750-3400934487415	LABORATOIRES CHAIX ET DU MARAIS	FR
Osmohale	SE/H/0711/001	40400	PHARMAXIS PHARMACEUTICALS LIMITED	DK
Osmohale inhalation powder, hard capsule	SE/H/0711/001	PA1382/1/1	PHARMAXIS PHARMACEUTICALS LIMITED	IE
Osmohale inhalation powder, hard capsule	SE/H/0711/001	PL 27944/0001	PHARMAXIS PHARMACEUTICALS LIMITED	UK
Osmohale, inhalatiepoeder in harde capsules	SE/H/0711/001	RVG 34641	PHARMAXIS PHARMACEUTICALS LIMITED	NL
Osmohale, polvere per inalazione, capsule rigide	SE/H/0711/001	038029017	PHARMAXIS PHARMACEUTICALS LIMITED	IT
Osmohale, polvo para inhalación (cápsulas duras)	SE/H/0711/001	69945	PHARMAXIS PHARMACEUTICALS LIMITED	ES