



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 June 2022
EMA/584606/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: polystyrene sulfonate

Procedure no.: PSUSA/00002472/202110



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
Resonium A Pulver	not available	15.583	SANOFI-AVENTIS GMBH OSTERREICH	AT
Resonium A Pulver	not available	15.583	SANOFI-AVENTIS GMBH OSTERREICH	AT
KAYEXALATE CALCIUM 14,99 g poeder voor orale of rectale suspensie	not available	BE043827	SANOFI BELGIUM	BE
KAYEXALATE CALCIUM 14,99 g poudre pour suspension buvable ou rectale.	not available	BE043827	SANOFI BELGIUM	BE
Kayexalate Calcium 14,99 g Pulver zur Herstellung einer Suspension zum Einnehmen oder einer Rektalsuspension	not available	BE043827	SANOFI BELGIUM	BE
KAYEXALATE SODIUM 14,99 g poeder voor orale of rectale suspensie	not available	BE043994	SANOFI BELGIUM	BE

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
KAYEXALATE SODIUM 14,99 g poudre pour suspension buvable ou rectale.	not available	BE043994	SANOFI BELGIUM	BE
Kayexalate Sodium 14,99 g Pulver zur Herstellung einer Suspension zum Einnehmen oder einer Rektalsuspension	not available	BE043994	SANOFI BELGIUM	BE
Sorbisterit, Poeder voor suspensie voor oraal / rectaal gebruik	NL/H/0901/001	BE302985	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	BE
Calcium Resonium prášek pro perorální /rektální suspenzi	not available	39/404/95-C	SANOFI-AVENTIS SRO	CZ
Resical prášek pro perorální/rektální suspenzi	NL/H/0901/001	39/372/07-C	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	CZ

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
Anti-Kalium Na, Granulat	not available	57930.00.00	MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	DE
Elutit®-Calcium-Granulat	not available	3000153.00.00	AGRARIA PHARMA GMBH	DE
Elutit®-Natrium-AS-Pulver	not available	3000149.00.00	AGRARIA PHARMA GMBH	DE
Resonium A 94–110 mg/g, Pulver zur Herstellung einer Suspension zum Einnehmen/Rektalsuspen sion	not available	6584573.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE

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
Resonium A 94–110 mg/g, Pulver zur Herstellung einer Suspension zum Einnehmen/Rektalsuspension	not available	6584573.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Resonium Calcium, pulver til oral suspension/rektalvæske, suspension	not available	05878	SANOFI A/S	DK
Sorbisterit, suukaudse/rektaalsuspension pulber	NL/H/0901/001	546307	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	EE
Resincalcio polvo para suspensión oral.	not available	46.726	LABORATORIOS RUBIÓ, S.A.	ES
RESINSODIO polvo para suspensión oral	not available	46.916	LABORATORIOS RUBIÓ, S.A.	ES

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
Sorbisterit polvo para suspensión oral/rectal	NL/H/0901/001	69234	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	ES
Resonium jauhe oraalisuspensiota/peräruisuspensiota varten	not available	5588	SANOFI OY	FI
Resonium pulver till oral/rektal suspension	not available	5588	SANOFI OY	FI
KAYEXALATE, poudre pour suspension orale et rectale	not available	34009 323 508 6 5	SANOFI-AVENTIS FRANCE	FR
POLYSTYRENE SULFONATE DE SODIUM ZENTIVA 400 g, poudre pour suspension orale et rectale	not available	34009 301 999 4 7	ZENTIVA FRANCE	FR

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
POLYSTYRENE SULFONATE DE SODIUM ZENTIVA 400 g, poudre pour suspension orale et rectale	not available	34009 301 999 4 7	ZENTIVA FRANCE	FR
RESIKALI, poudre pour suspension orale/rectale	NL/H/0901/001	NL33723	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	FR
Xaviox 14,96 g prašak za oralnu suspenziju u vrećici	not available	HR-H-870909668	MAKPHARM D.O.O.	HR
Resonium por belsőleges szuszpenzióhoz vagy végbélszuszpenzióhoz	not available	OGYI-T-1210/01	SANOFI-AVENTIS ZRT	HU
Calcium Resonium 99.934% w/w Powder for Oral or Rectal Suspension	not available	PA 540/141/1	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	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
KAYEXALATE polvere per sospensione orale e rettale	not available	021394022	SANOFI S.R.L.	IT
Sorbisterit, polvere per sospensione orale/rettale	NL/H/0901/001	039564012	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	IT
KAYEXALATE CALCIUM 14,99 g poudre pour suspension buvable ou rectale.	not available	0061622	SANOFI BELGIUM	LU
KAYEXALATE SODIUM 14,99 g poudre pour suspension buvable ou rectale	not available	0061636	SANOFI BELGIUM	LU
Calcium Resonium 99.934% w/w Powder for Oral or Rectal Suspension	not available	MA1359/01301	SANOFI S.R.L.	MT
Natriumpolystyreensulfo naat 1 g/g Focus, poeder voor suspensie voor oraal / rectaal gebruik	not available	RVG 125575	FOCUS CARE PHARMACEUTICALS B.V.	NL

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
Resonium A, poeder	not available	RVG 08071	GENZYME EUROPE B.V.	NL
Sorbisterit, poeder voor orale/rectale suspensie 90% m/m	NL/H/0901/001	RVG 10261	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	NL
Resonium-Calcium 1 g/g, pulver til mikstur/rektalvæske, suspensjon	not available	5552	SANOFI-AVENTIS NORGE AS	NO
CALCIUM RESONIUM 1,2 g jonów wapnia/15 g, proszek doustny lub do sporządzania	not available	R/3762	SANOFI-AVENTIS FRANCE	PL
RESONIUM A 1,42 g jonów sodu/15 g, proszek doustny lub do sporządzania zawiesiny doodbytniczej	not available	R/3763	SANOFI-AVENTIS FRANCE	PL

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
Resical, pó para suspensão oral ou retal	NL/H/0901/001	5049978	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	PT
Resonium 454 g Granulado para suspensão oral ou retal	not available	8250704	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Resonium pulver till oral/rektal suspension	not available	7274	SANOFI AB	SE
Calcium Resonium 999,34 mg/g prášok na perorálnu/rektálnu suspenziu	not available	87/0749/95-S	SANOFI-AVENTIS GROUPE	SK
Sorbisterit, prášok na perorálnu/rektálnu suspenziu	NL/H/0901/001	87/0149/07-S	FRESENIUS MEDICAL CARE NEPHROLOGICA DEUTSCHLAND GMBH	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
Calcium Polystyrene Sulfonate 99.934% w/w Powder for Oral/Rectal Suspension	not available	PL 49578/0011	ROMA PHARMACEUTICALS LIMITED	XI
Calcium Resonium 99.934% w/w Powder for Oral/Rectal Suspension	not available	PL 04425/0620	AVENTIS PHARMA LTD	XI
Resoncalcium 99.75% Powder for Oral/Rectal Suspension	not available	PL 06464/3119	WAYMADE PLC	XI
Resonium A.	not available	PL 04425/0178	AVENTIS PHARMA LTD	XI