



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2017
EMA/776067/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): fenspiride

Procedure No.: PSUSA/00001368/201704



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
EPISTAT 80 mg comprimate cu eliberare prelungită	not available	9493/2016/01	GEDEON RICHTER ROMÂNIA S.A.	RO
EPISTAT 80 mg comprimate cu eliberare prelungită	not available	9493/2016/02	GEDEON RICHTER ROMÂNIA S.A.	RO
EPISTAT 80 mg comprimate cu eliberare prelungită	not available	9493/2016/03	GEDEON RICHTER ROMÂNIA S.A.	RO
Eurefin, 2 mg/ml, syrop	not available	21095	HASCO-LEK	PL
Eurespal 2 mg/ml sirop	not available	1198/2008/01	LES LABORATOIRES SERVIER (SURESNES)	RO
EURESPAL 80 mg comprimate cu eliberare prelungită	not available	667/2008/01	LES LABORATOIRES SERVIER (SURESNES)	RO
EURESPAL 80 mg tabletki powlekane	not available	7481	LES LABORATOIRES SERVIER	PL
Fenspogal, 2 mg/ml, syrop	not available	15970	FARMACEUTYCZNA SPOLDZIELNIA PRACY GALENA	PL
Fosidal o smaku malinowym, 2 mg/ml, syrop	PL/H/0302/001	22566	MEDANA PHARMA SPOLKA AKCYJNA	PL
Fosidal o smaku pomarańczowym, 2 mg/ml, syrop	not available	18233	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Fosidal PPH, 80 mg, tabletki powlekane	not available	18821	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Kudorp 2 mg/ml sirupas	PL/H/0302/001	LT/1/15/3728/001	MEDANA PHARMA SPOLKA AKCYJNA	LT
Kudorp 2 mg/ml sirups	PL/H/0302/001	15-0063	MEDANA PHARMA SPOLKA AKCYJNA	LV
PNEUMOREL 0.2 POUR	not available	313 797.5	LES LABORATOIRES SERVIER	FR

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CENT, sirop			(SURESNES)	
PNEUMOREL 0.2 POUR CENT, sirop	not available	313 798.1	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL 0.2 POUR CENT, sirop	not available	313 799.8	LES LABORATOIRES SERVIER (SURESNES)	FR
Pneumorel 2 mg/ml Xarope	not available	9435420	SERVIER PORTUGAL, ESPECIALIDADES FARMACÉUTICAS, LDA.	PT
PNEUMOREL 80MG, comprimé enrobé	not available	319 295.1	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL 80MG, comprimé enrobé	not available	319 299.7	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL 80MG, comprimé enrobé	not available	319 297.4	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL 80MG, comprimé enrobé	not available	319 298.0	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL 80MG, comprimé enrobé	not available	319 296.8	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL 80MG, comprimé enrobé	not available	319 300.5	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL 80MG, comprimé enrobé	not available	319 294.5	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL 80MG, comprimé enrobé	not available	319 301.1	LES LABORATOIRES SERVIER (SURESNES)	FR
Pneumorel Retard 80 mg Comprimido gastrorresistente	not available	9435313	SERVIER PORTUGAL, ESPECIALIDADES FARMACÉUTICAS, LDA.	PT
Pulneo, 2 mg/ml, syrop	not available	15187	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
Pulneo, 25 mg/ml, krople doustne, roztwór	not available	18107	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
Pulneo, 25 mg/ml, krople doustne, roztwór	not available	18107	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
ЕУРЕСПАЛ 0,2% сироп	not available	20030278	LES LABORATOIRES SERVIER (SURESNES)	BG
ЕУРЕСПАЛ 80 mg таблетки с удължено освобождаване	not available	20030279	LES LABORATOIRES SERVIER (SURESNES)	BG

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Сиресп 2 мг/мл сироп	PL/H/0302/001	20150296	MEDANA PHARMA SPOLKA AKCYJNA	BG