



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

London, 14 November 2018
EMA/25401/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fenspiride

Procedure no.: PSUSA/00001368/201804



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
EURESPAL 80 mg comprimate cu eliberare prelungită	not available	667/2008/01	LES LABORATOIRES SERVIER (SURESNES)	RO
Eurespal 2 mg/ml sirop	not available	1198/2008/01	LES LABORATOIRES SERVIER (SURESNES)	RO
Pulneo, 25 mg/ml, krople doustne, roztwór	not available	18107	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
Pulneo o smaku coli, 2 mg/ml, syrop	not available	22822	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
EURESPAL 80 mg comprimate cu eliberare prelungită	not available	667/2008/01	LES LABORATOIRES SERVIER (SURESNES)	RO
Fenspogal, 2 mg/ml, syrop	not available	15970	FARMACEUTYCZNA SPOLDZIELNIA PRACY GALENA	PL
Pulneo o smaku coli, 2 mg/ml, syrop	not available	22822	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
Pneumorel Retard 80 mg Comprimido gastrorresistente	not available	9435313	SERVIER PORTUGAL, ESPECIALIDADES FARMACÊUTICAS, LDA.	PT
Kudorp 2 mg/ml sirups	PL/H/0302/001	15-0063	MEDANA PHARMA SPOLKA AKCYJNA	LV
Kudorp 2 mg/ml sirupas	PL/H/0302/001	LT/1/15/3728/001	MEDANA PHARMA SPOLKA AKCYJNA	LT
Fosidal o smaku pomarańczowym, 2	not available	18233	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA	PL

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mg/ml, syrop			AKCYJNA	
Сиресп 2 mg/ml сироп	PL/H/0302/001	20150296	MEDANA PHARMA SPOLKA AKCYJNA	BG
Pulneo, 2 mg/ml, syrop	not available	15187	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
ЕУРЕСПАЛ 0,2% сироп	not available	20030278	LES LABORATOIRES SERVIER (SURESNES)	BG
Pulneo, 2 mg/ml, syrop	not available	15187	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
EURESPAL 80 mg tabletki powlekane	not available	7481	LES LABORATOIRES SERVIER	PL
ЕУРЕСПАЛ 80 mg таблетки с удължено освобождаване	not available	20030279	LES LABORATOIRES SERVIER (SURESNES)	BG
PNEUMOREL® 80 mg, comprimé enrobé.	not available	319 295-1	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL® 80 mg, comprimé enrobé.	not available	319 299-7	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL® 80 mg, comprimé enrobé.	not available	319 297-4	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL® 80 mg, comprimé enrobé.	not available	319 298-0	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL® 80 mg, comprimé enrobé.	not available	319 296-8	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL® 80 mg, comprimé enrobé.	not available	319 300-5	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL® 80 mg, comprimé enrobé.	not available	319 294-5	LES LABORATOIRES SERVIER (SURESNES)	FR
PNEUMOREL® 80 mg, comprimé enrobé.	not available	319 301-1	LES LABORATOIRES SERVIER (SURESNES)	FR
Eurefin, 2 mg/ml, syrop	not available	21095	HASCO-LEK	PL
Pneumorel 2 mg/ml Xarope	not available	9435420	SERVIER PORTUGAL, ESPECIALIDADES FARMACÉUTICAS, LDA.	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
PNEUMOREL® 0,2 POUR CENT, sirop.	not available	313 797-5	LES LABORATOIRES SERVIER (SURESNES)	FR
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