



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2022
EMA/738449/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: nifuroxazide

Procedure no.: PSUSA/00002160/202108



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
PANFUREX 4%, suspension buvable	not available	34009 327 559 4 3	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 267 050 3 9	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 327 558 8 2	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 554 915 6 9	BOUCHARA RECORDATI	FR
PANFURYL 200 mg, gélule	not available	34009 347 745 8 4	BOUCHARA RECORDATI	FR
PANFUREX Gé 4 %, suspension buvable	not available	0182601	BOUCHARA RECORDATI	LU
PANFUREX 200 mg, gélule	not available	0182595	BOUCHARA RECORDATI	LU
ERCEFURYL 200 mg, gélule	not available	34009 381 125 9 7	OPELLA HEALTHCARE FRANCE SAS	FR
NIFUROKSAZYD POLFARMEX, 100 mg, tabletki powlekane	not available	23419	POLFARMEX S.A.	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
NIFUROKSAZYD POLFARMEX, 200 mg, tabletki powlekane	not available	23423	POLFARMEX S.A.	PL
NIFUROKSAZYD POLFARMEX, 220 mg/5 ml, zawiesina doustna	not available	23424	POLFARMEX S.A.	PL
DIAFURYL 200 mg, gélule	not available	34009 354 889 1 6	COOPERATION PHARMACEUTIQUE FRANCAISE	FR
DIAFURYL 200 mg, gélule	not available	34009 354 889 1 6	COOPERATION PHARMACEUTIQUE FRANCAISE	FR
DIAFURYL 200 mg, gélule	not available	34009 354 889 1 6	COOPERATION PHARMACEUTIQUE FRANCAISE	FR
ZYFURAX BABY, 220 mg/5 ml, zawiesina doustna	not available	21801	HASCO-LEK	PL
NIFUROKSAZYD 200 HASCO, 200 mg, tabletki powlekane	not available	14139	HASCO-LEK	PL
NIFUROKSAZYD HASCO 100 mg tabletki powlekane	not available	10897	HASCO-LEK	PL
NIFUROKSAZYD HASCO 220 mg/5 ml zawiesina doustna	not available	8346	HASCO-LEK	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
ZYFURAX JUNIOR, 100 mg, tabletki powlekane	not available	18332	HASCO-LEK	PL
ZYFURAX FORTE, 200 mg, tabletki powlekane	not available	18545	HASCO-LEK	PL
NIFUROXAZIDE EG LABO CONSEIL 200 mg, gélule	not available	NL24961	EG LABO LABORATOIRES EUROGENERICS	FR
ERCEFURYL	not available	21203/24-07-1991	SANOFI-AVENTIS AEBE	GR
ERCEFURYL□	not available	21204/24-07-1991	SANOFI-AVENTIS AEBE	GR
ERCEFURYL	not available	21203/24-07-1991	SANOFI-AVENTIS AEBE	GR
ERCEFURYL	not available	21203/24-07-1991	SANOFI-AVENTIS AEBE	GR
ERCEFURYL 200 mg, gélule	not available	34009 381 125 9 7	OPELLA HEALTHCARE FRANCE SAS	FR
NIFUROKSAZYD GEDEON RICHTER, 100 mg, tabletki powlekane	not available	R/1109	GEDEON RICHTER POLSKA SP. Z. O.O.	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
ERCEFURYL 200 mg, gélule	not available	34009 381 125 9 7	OPELLA HEALTHCARE FRANCE SAS	FR
BACTÉRIX 200 mg, gélule	not available	34009 359 587 3 0	GIFRER BARBEZAT	FR
NIFUROXAZIDE ARROW 200 mg, gélule	not available	NL 27010	ARROW GENERIQUES	FR
DIAFURYL 200 mg, gélule	not available	34009 354 889 1 6	COOPERATION PHARMACEUTIQUE FRANCAISE	FR
PANFUREX 4%, suspension buvable	not available	34009 327 559 4 3	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 267 050 3 9	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 327 558 8 2	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 554 915 6 9	BOUCHARA RECORDATI	FR
PANFURYL 200 mg, gélule	not available	34009 347 745 8 4	BOUCHARA RECORDATI	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
PANFUREX Gé 4 %, suspension buvable	not available	0182601	BOUCHARA RECORDATI	LU
PANFUREX 200 mg, gélule	not available	0182595	BOUCHARA RECORDATI	LU
Ercefuryl 200 mg tvrdé tobolky	not available	42/622/97-C	TAKEDA GMBH	CZ
NIFUROXAZIDE ARROW 200 mg, gélule	not available	NL 27010	ARROW GENERIQUES	FR
NIFUROXAZIDE ZENTIVA 200 mg, gélule	not available	34009 324 163 2 5	ZENTIVA FRANCE	FR
NIFUROXAZIDE ZENTIVA 200 mg, gélule	not available	34009 367 469 6 1	ZENTIVA FRANCE	FR
NIFUROXAZIDE ZENTIVA 200 mg, gélule	not available	34009 324 164 9 3	ZENTIVA FRANCE	FR
Nifuroxazide Teva 200 mg, gelule	not available	NL23914	TEVA SANTÉ	FR
NIFUROXAZIDE ARROW 200 mg, gélule	not available	NL 27010	ARROW GENERIQUES	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
ERCEFURYL 200 mg, gélule	not available	34009 381 125 9 7	OPELLA HEALTHCARE FRANCE SAS	FR
DIARINE Πόσιμο Εναιώρημα 220 mg/5 ml	not available	39989/08/15-12-2017	LAVIPHARM S.A	GR
NIFUROKSAZYD POLFARMEX, 100 mg, tabletki powlekane	not available	23419	POLFARMEX S.A.	PL
NIFUROKSAZYD POLFARMEX, 200 mg, tabletki powlekane	not available	23423	POLFARMEX S.A.	PL
NIFUROKSAZYD POLFARMEX, 220 mg/5 ml, zawiesina doustna	not available	23424	POLFARMEX S.A.	PL
NIFUROKSAZYD GEDEON RICHTER, 220 mg/5 ml, zawiesina doustna	not available	R/1108	GEDEON RICHTER POLSKA SP. Z. O.O.	PL
ERCEFURYL	not available	21203/24-07-1991	SANOFI-AVENTIS AEBE	GR
ERCEFURYL□	not available	21204/24-07-1991	SANOFI-AVENTIS AEBE	GR
ERCEFURYL	not available	21203/24-07-1991	SANOFI-AVENTIS AEBE	GR

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
ERCEFURYL	not available	21203/24-07-1991	SANOFI-AVENTIS AEBE	GR
PANFUREX 4%, suspension buvable	not available	34009 327 559 4 3	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 267 050 3 9	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 327 558 8 2	BOUCHARA RECORDATI	FR
PANFUREX 200 mg, gélule	not available	34009 554 915 6 9	BOUCHARA RECORDATI	FR
PANFURYL 200 mg, gélule	not available	34009 347 745 8 4	BOUCHARA RECORDATI	FR
PANFUREX Gé 4 %, suspension buvable	not available	0182601	BOUCHARA RECORDATI	LU
PANFUREX 200 mg, gélule	not available	0182595	BOUCHARA RECORDATI	LU
ERCEFURYL 200 mg, gélule	not available	34009 381 125 9 7	OPELLA HEALTHCARE FRANCE SAS	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
NIFUROKSAZYD GEDEON RICHTER, 200 mg, kapsułki twarde	not available	17650	GEDEON RICHTER POLSKA SP. Z. O.O.	PL
NIFUROXAZIDE MYLAN 200 mg, gélule	not available	NL 23062	MYLAN S.A.S	FR
Ercefuryl 200 mg tvrdé tobolky	not available	42/622/97-C	TAKEDA GMBH	CZ
ERCEFURYL 200 mg, gélule	not available	34009 381 125 9 7	OPELLA HEALTHCARE FRANCE SAS	FR
DIAFURYL 200 mg, gélule	not available	34009 354 889 1 6	COOPERATION PHARMACEUTIQUE FRANCAISE	FR
NIFUROKSAZYD POLFARMEX, 100 mg, tabletki powlekane	not available	23419	POLFARMEX S.A.	PL
NIFUROKSAZYD POLFARMEX, 200 mg, tabletki powlekane	not available	23423	POLFARMEX S.A.	PL
NIFUROKSAZYD POLFARMEX, 220 mg/5 ml, zawiesina doustna	not available	23424	POLFARMEX S.A.	PL
NIFUROXAZIDE TEVA CONSEIL 200 mg, gélule	not available	NL28935	TEVA SANTÉ	FR