



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 November 2020
EMA/646694/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: aceclofenac

Procedure no.: PSUSA/00000022/202003



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
Aflamil 100 mg comprimate filmate	not available	6250/2014/03	GEDEON RICHTER ROMÂNIA S.A.	RO
Aflamil 100 mg comprimate filmate	not available	6250/2014/01	GEDEON RICHTER ROMÂNIA S.A.	RO
Aflamil 100 mg comprimate filmate	not available	6250/2014/02	GEDEON RICHTER ROMÂNIA S.A.	RO
Aflamil 100 mg film-coated tablets	not available	20060070	GEDEON RICHTER PLC.	BG
Aflamil 100 mg filmom obalené tablety	not available	29/0134/04-S	GEDEON RICHTER PLC.	SK
AFLAMIL 100 mg prášok na perorálnu suspenziu	not available	29/0036/13-S	GEDEON RICHTER PLC.	SK
AFLAMIL 100 mg pulbere pentru suspensie orală în plic	not available	12490/2019/01	GEDEON RICHTER ROMÂNIA S.A.	RO
AFLAMIL 100 mg pulbere pentru suspensie orală în plic	not available	12490/2019/01	GEDEON RICHTER ROMÂNIA S.A.	RO
AFLAMIL 15 mg/g cremă	not available	12491/2019/01	GEDEON RICHTER ROMÂNIA S.A.	RO

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
AFLAMIL 15 mg/g krém	not available	29/0037/13-S	GEDEON RICHTER PLC.	SK
Aflamin 100 mg filmdobéta	not available	OGYI-T-6689/01	GEDEON RICHTER PLC.	HU
Aflamin 100 mg filmdobéta	not available	OGYI-T-6689/03	GEDEON RICHTER PLC.	HU
Aflamin 100 mg filmdobéta	not available	OGYI-T-6689/04	GEDEON RICHTER PLC.	HU
Aflamin krém	not available	OGYI-T-6689/05	GEDEON RICHTER PLC.	HU
Aflamin Rapid 100 mg por belsősleges szuszpenzióhoz	not available	OGYI-T-6689/07	GEDEON RICHTER PLC.	HU
Aflamin Rapid 100 mg por belsősleges szuszpenzióhoz	not available	OGYI-T-6689/06	GEDEON RICHTER PLC.	HU
AIRTAL 1,5 g / 100 g crema	not available	032773057	ALMIRALL, S.A.	IT
Airtal 100 mg apvalkotás tabletes	not available	04-0106	GEDEON RICHTER PLC.	LV

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
AIRTAL 100 mg comprime rivestite	not available	032773069	ALMIRALL, S.A.	IT
AIRTAL 100 mg comprime rivestite	not available	032773020	ALMIRALL, S.A.	IT
Air-tal 100 mg comprimés pelliculés	not available	BE177493	ALMIRALL, S.A.	BE
Air-tal 100 mg comprimés pelliculés	not available	2008069811	ALMIRALL, S.A.	LU
AIRTAL 100 mg Comprimidos recubiertos con película	not available	59.024	ALMIRALL, S.A.	ES
Airtal 100 mg comprimidos revestidos por película	not available	5267455	ALMIRALL, S.A.	PT
Airtal 100 mg comprimidos revestidos por película	not available	5267463	ALMIRALL, S.A.	PT
Air-tal 100 mg filmomhulde tabletten	not available	BE177493	ALMIRALL, S.A.	BE
Air-tal 100 mg Filmtabletten	not available	BE177493	ALMIRALL, S.A.	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
Airtal 100 mg pó para suspensão oral	not available	5267471	ALMIRALL, S.A.	PT
AIRTAL 100 mg polvere per sospensione orale	not available	032773032	ALMIRALL, S.A.	IT
AIRTAL 100 mg polvere per sospensione orale	not available	032773032	ALMIRALL, S.A.	IT
AIRTAL 100 mg Polvo para suspensión oral	not available	60.695	ALMIRALL, S.A.	ES
Airtal 15 mg/g krēms	not available	11-0249	GEDEON RICHTER PLC.	LV
AIRTAL DIFUCREM 15 mg/g Crema	not available	60.191	ALMIRALL, S.A.	ES
Airtal Difucreme 15 mg/g creme	not available	5267505	ALMIRALL, S.A.	PT
Airtal100 mg film-coated tablets	not available	16332	ALMIRALL, S.A.	CY
Barcan 100 mg filmdragerade tabletter	SE/H/0122/001	12507	ALMIRALL, S.A.	SE

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
Beofenac® 100 mg Filmtabletten	SE/H/0122/001	41231.00.00	ALMIRALL, S.A.	DE
Biofenac 100 mg comprimés pelliculés	not available	BE249584	ALMIRALL, S.A.	BE
Biofenac 100 mg comprimés pelliculés	not available	BE249584	ALMIRALL, S.A.	BE
Biofenac 100 mg comprimés pelliculés	not available	2008069805	ALMIRALL, S.A.	LU
Biofenac 100 mg comprimés pelliculés	not available	2008069805	ALMIRALL, S.A.	LU
Biofenac 100 mg comprimidos revestidos por película	not available	5268362	ALMIRALL, S.A.	PT
Biofenac 100 mg comprimidos revestidos por película	not available	5268370	ALMIRALL, S.A.	PT
Biofenac 100 mg filmomhulde tabletten	not available	BE249584	ALMIRALL, S.A.	BE
Biofenac 100 mg Filmtabletten	not available	BE249584	ALMIRALL, S.A.	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
Biofenac 100 mg pó para suspensão oral	not available	5269022	ALMIRALL, S.A.	PT
BIOFENAC 100, omhulde tabletten 100 mg	not available	RVG 19207	ALMIRALL, S.A.	NL
Biofenac 15 mg/g creme	not available	5269113	ALMIRALL, S.A.	PT
BIOFENAC® 1,5 % w/w κρέμα	not available	8524/06-02/2007	GALENICA SA	GR
CARTREX 100 mg, comprimé pelliculé	not available	34009 345 665 7 8	ALMIRALL, SAS	FR
CARTREX 100 mg, comprimé pelliculé	not available	34009 347 409 8 5	ALMIRALL, SAS	FR
CARTREX 100 mg, comprimé pelliculé	not available	34009 560 894 7 5	ALMIRALL, SAS	FR
Gerbin 100 mg Comprimidos recubiertos con película	not available	59.026	LABORATORIOS ALMIRALL, S.L.	ES
GLADIO 1.5 g/100 g crema	not available	031220054	ABIOGEN PHARMA S.P.A.	IT

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
GLADIO 100 mg comprese rivestite	not available	031220015	ABIOGEN PHARMA S.P.A.	IT
GLADIO 100 mg comprese rivestite	not available	031220066	ABIOGEN PHARMA S.P.A.	IT
GLADIO 100 mg polvere per sospensione orale	not available	031220027	ABIOGEN PHARMA S.P.A.	IT
KAFENAC 1,5 g/100 g crema	not available	031842053	ALMIRALL, S.A.	IT
KAFENAC 100 mg comprese rivestite	not available	031842065	ALMIRALL, S.A.	IT
KAFENAC 100 mg comprese rivestite	not available	031842014	ALMIRALL, S.A.	IT
PRESERVEX® film-coated tablets 100 mg	not available	PL 16973/0001	ALMIRALL, S.A.	UK
BIOFENAC 100 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	13384/14/17-10-2016	GALENICA SA	GR
Афламил 100 mg прах за перорална суспензия	not available	20110204	GEDEON RICHTER PLC.	BG

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
Афламил 15 mg/g крем	not available	20110464	GEDEON RICHTER PLC.	BG