



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2018
EMA/382206/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): naproxen

Procedure No.: PSUSA/00002125/201708



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
MOMENDOL 220 mg plévele dengtos tabletès	not available	LT/1/04/0014/001	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	LT
MOMENDOL 220 mg plévele dengtos tabletès	not available	LT/1/04/0014/002	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	LT
Eox 220 mg filmdragerade tabletter	IT/H/0110/001	16998	MEDA OTC AB	FI
Momendol, filmomhulde tabletten 220 mg	IT/H/0110/001	RVG 27361	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	NL
Momendol 220 mg - Filmtabletten	IT/H/0110/001	1-24912	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	AT
MOMENDOL 220 mg comprimés pelliculés	IT/H/0110/001	1234/02/070066	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	LU
Momendol 220 mg film-coated tablets	IT/H/0110/001	PA 959/2/1	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IE
Momendol 220 mg Filmtabletten	IT/H/0110/001	53767.00.00	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	DE
MOMENDOL 220 mg compresse rivestite con film	IT/H/0110/001	025829185	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
MOMENDOL 220 mg compresse rivestite con film	IT/H/0110/001	025829084	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
Momendol comprimidos revestidos por película	IT/H/0110/001	4031381	ANGELINI FARMACÊUTICA, LDA	PT
Momendol comprimidos revestidos por película	IT/H/0110/001	5814082	ANGELINI FARMACÊUTICA, LDA	PT
Momendol 220 mg επικαλυμμένα με λεπτό υμένιο δισκία	IT/H/0110/001	28382/20-4-2011	ANGELINI PHARMA HELLAS S.A.	GR
Eox 220 mg filmdragerade tabletter	IT/H/0110/001	18008	MEDA OTC AB	SE
Eox 220 mg kalvopäälysteinen tabletti	IT/H/0110/001	16998	MEDA OTC AB	FI
Eox	IT/H/0110/001	33253	MEDA OTC AB	DK

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Naproxen Saft InfectoPharm® 250 mg/5 ml Suspension zum Einnehmen	not available	17.522	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	AT
Proxen® 500 mg - Filmtabletten	not available	1-7231	GRÜNENTHAL GES. M.B.H.	AT
NAPSYN	not available	29/0729/92-S	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SK
NAPREBEN 550 mg capsule rigide	not available	027669011	MERCURIO PHARMA S.R.L.	IT
NAPREBEN 10% gel	not available	027669050	MERCURIO PHARMA S.R.L.	IT
MOMENDOL 10% w/w GEL	IT/H/0110/002	PA0959/002/002	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IE
MOMENDOL 10% gel	IT/H/0110/002	025829197	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
MOMENDOL 10% gel	IT/H/0110/002	025829209	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
Momendol 100 mg/g (10%) gel	IT/H/0110/002	5359559	ANGELINI FARMACÊUTICA, LDA	PT
Momendol 100 mg/g (10%) gel	IT/H/0110/002	5359567	ANGELINI FARMACÊUTICA, LDA	PT
MOMENDOL 10% w/w GEL	IT/H/0110/002	34588/14-5-2012	ANGELINI PHARMA HELLAS S.A.	GR
Synflex 550 mg compresse rivestite	not available	024722047	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Naprosyn 10% gel	not available	023177102	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Naprosyn 250 mg compresse gastroresistenti	not available	023177203	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Naprosyn 500 mg compresse gastroresistenti	not available	023177215	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Naprosyn 500 mg supposte	not available	023177088	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Naprosyn 250 mg granulato per sospensione orale	not available	023177090	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Naprosyn 500 mg granulato per sospensione orale	not available	023177138	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Naprosyn 750 mg compresse a rilascio modificato	not available	023177189	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Synflex 275 mg capsule rigide	not available	024722011	RECORDATI INDUSTRIA CHIMICA E	IT

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			FARMACEUTICA S.P.A.	
Synflex 550 mg compresse rivestite	not available	024722112	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Synflex 550 mg granulato per sospensione orale	not available	024722086	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Naproxen 500mg Tablets	not available	PL 44041/0026	NOUMED LIFE SCIENCES	UK
Laser 750 mg compresse a rilascio controllato	not available	023886082	EURO-PHARMA S.R.L.	IT
Naproxen Sandoz 500 mg tabletten	not available	BE273883	SANDOZ N.V.	BE
Naproxen Sandoz 250 mg tabletten	not available	BE274687	SANDOZ N.V.	BE
Naprosyn 250 mg tabletta	not available	OGYI-T- 3556/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Dolormin® GS mit Naproxen 250 mg tabletten	not available	35876.00.00	JOHNSON & JOHNSON GMBH	DE
Dolormin® für Frauen bei Menstruationsbeschwerden mit Naproxen	not available	35873.00.00	JOHNSON & JOHNSON GMBH	DE
Dolormin® für Frauen bei Menstruationsbeschwerden mit Naproxen	not available	35873.00.00	JOHNSON & JOHNSON GMBH	DE
Dolormin® für Frauen bei Menstruationsbeschwerden mit Naproxen	not available	35873.00.00	JOHNSON & JOHNSON GMBH	DE
Dolormin® GS mit Naproxen 250 mg tabletten	not available	35876.00.00	JOHNSON & JOHNSON GMBH	DE
Dolormin® GS mit Naproxen 250 mg tabletten	not available	35876.00.00	JOHNSON & JOHNSON GMBH	DE
PREXAN "500 mg compresse"	not available	024467058	NEW RESEARCH SRL	IT
PREXAN "500 mg granulato per sospensione orale"	not available	024467108	NEW RESEARCH SRL	IT
PREXAN 10% Crema	not available	024467084	NEW RESEARCH SRL	IT
Naproxen Apotex 250 mg, zetpillen	not available	RVG 57649	APOTEX EUROPE B.V.	NL
Naproxen Apotex 500 mg, zetpillen	not available	RVG 57650	APOTEX EUROPE B.V.	NL
ALEVE 220 mg, Filmtabletten	not available	BE 198213	BAYER SA NV	BE
Lasonil antinfiammatorio e antireumatico 220 mg compresse rivestite con film	not available	032790040	BAYER SPA	IT

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Lasonil antinfiammatorio e antireumatico 220 mg compresse rivestite con film	not available	032790038	BAYER SPA	IT
Aleve filtabletta	not available	OGYI-T-8021/03	BAYER HUNGARIA KFT	HU
Aleve filtabletta	not available	OGYI-T-8021/04	BAYER HUNGARIA KFT	HU
Aleve filtabletta	not available	OGYI-T-8021/05	BAYER HUNGARIA KFT	HU
Aleve filtabletta	not available	OGYI-T-8021/01	BAYER HUNGARIA KFT	HU
ALEVE 220 mg, Filmbtabletten	not available	2000090015	BAYER SA NV	LU
Lasonil antinfiammatorio e antireumatico 660 mg compresse a rilascio modificato	not available	032790053	BAYER SPA	IT
Lasonil antinfiammatorio e antireumatico 660 mg compresse a rilascio modificato	not available	032790065	BAYER SPA	IT
Lasonil antinfiammatorio e antireumatico 660 mg compresse a rilascio modificato	not available	032790077	BAYER SPA	IT
ALEVETABS 220 mg, comprimé pelliculé	not available	34009 274 544 8 6	BAYER HEALTHCARE	FR
ALEVETABS 220 mg, comprimé pelliculé	not available	34009 274 286 9 2	BAYER HEALTHCARE	FR
ALEVETABS 220 mg, comprimé pelliculé	not available	34009 350 622 0 8	BAYER HEALTHCARE	FR
ALEVE 220 mg, comprimé pelliculé	not available	34009 274 295 8 3	BAYER HEALTHCARE	FR
ALEVE 220 mg, comprimé pelliculé	not available	34009 379 191 8 0	BAYER HEALTHCARE	FR
ALEVE 220 mg, comprimé pelliculé	not available	34009 492 050 7 3	BAYER HEALTHCARE	FR
ALEVE 220 mg, comprimé pelliculé	not available	34009 379 192 4 1	BAYER HEALTHCARE	FR
Aleve Extra 660 mg retard tabletta	not available	OGYI-T-8021/06	BAYER HUNGARIA KFT	HU
Aleve Extra 660 mg retard tabletta	not available	OGYI-T-8021/08	BAYER HUNGARIA KFT	HU
Aleve Extra 660 mg retard tabletta	not available	OGYI-T-8021/07	BAYER HUNGARIA KFT	HU
Feminax® Ultra 250mg Gastro-Resistant Tablets	not available	PL 00010/0631	BAYER PLC	UK
Aleve filtabletta	not available	OGYI-T-8021/02	BAYER HUNGARIA KFT	HU
Aleve Feminax bij menstruatiepijn 275	not available	RVG 09006	BAYER BV	NL
ALEVE	not available	62.707	BAYER HISPANIA SL	ES
Aleve Select 275 mg, omhulde tabletten	not available	RVG 09007	BAYER BV	NL
ALEVE® - Filmbtabletten	not available	1-22747	BAYER AUSTRIA GMBH	AT
Lasonil antinfiammatorio e antireumatico 220 mg compresse rivestite con film	not available	032790014	BAYER SPA	IT
Lasonil antinfiammatorio e antireumatico 220 mg compresse rivestite con film	not available	032790026	BAYER SPA	IT
ALEVE 220 mg comprimés pelliculés	not available	2000090015	BAYER SA NV	LU

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ALEVE 220 mg filmomhulde tabletten	not available	BE 198213	BAYER SA NV	BE
ALEVE 220 mg comprimés pelliculés	not available	BE 198213	BAYER SA NV	BE
Aktren Naproxen Filmtablette mit 220 mg Naproxen-Natrium	not available	38459.00.00	BAYER VITAL GMBH	DE
Aleve® Filmtablette mit 220 mg Naproxen-Natrium	not available	38457.00.00	BAYER VITAL GMBH	DE
Aleve® Wirkstoff: Naproxen-Natrium	not available	38458.00.00	BAYER VITAL GMBH	DE
Aleve, 220 mg, tabletki powlekane	not available	7756	BAYER SP.Z.O.O	PL
Aleve Intense 550 mg, omhulde tablet	not available	RVG 14484	BAYER BV	NL
ALEVETABS 220 mg, comprimé pelliculé	not available	34009 350 621 4 7	BAYER HEALTHCARE	FR
ALEVE 220 mg, comprimé pelliculé	not available	34009 380 481 6 2	BAYER HEALTHCARE	FR
Aleve Classic bij pijn en koorts 220, omhulde tabletten	not available	RVG 19630	BAYER BV	NL
NAPROSYN 10 %, γέλη	not available	65484/13/7-2-2014	MINERVA PHARMACEUTICAL S.A	GR
NAPROSYN 250 mg, γαστροανθεκτικό δισκίο	not available	23554/12-3-14	MINERVA PHARMACEUTICAL S.A	GR
NAPROSYN 500 mg, γαστροανθεκτικό δισκίο	not available	21622/12-3-14	MINERVA PHARMACEUTICAL S.A	GR
NAPROSYN 250 mg, δισκία	not available	60295/13/22-5-2014	MINERVA PHARMACEUTICAL S.A	GR
NAPROSYN 500 mg, δισκία	not available	45244/22-5-2014	MINERVA PHARMACEUTICAL S.A	GR
ANAPROX 550mg δισκία επικαλυμμένα	not available	85120/10-11-2014	MINERVA PHARMACEUTICAL S.A	GR
NAPROSYN 250 mg, υπόθετα	not available	79750/09/7-4-10	MINERVA PHARMACEUTICAL S.A	GR
NAPROSYN 500 mg, υπόθετα	not available	21344/7-4-10	MINERVA PHARMACEUTICAL S.A	GR
Miranax® 550 mg - Filmtabletten	not available	1 - 19930	GRÜNENTHAL GES. M.B.H.	AT
Момендол 220 mg филмирани таблетки	not available	20050220	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	BG
Apranax 275 mg filmtabletta	not available	OGYI-T- 3742/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Apranax 550 mg filmtabletta	not available	OGYI-T- 4030/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Apranax 275 mg filmtabletta	not available	OGYI-T- 3742/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Apranax 550 mg filmtabletta	not available	OGYI-T- 4030/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
NAPRIUS 10% GEL	not available	024667141	AESULAPIUS FARMACEUTICI S.R.L.	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
NAPRIUS 500 mg Compresse	not available	024667139	AESULAPIUS FARMACEUTICI S.R.L.	IT
NAPRIUS 500 mg Granulato per sospensione orale	not available	024667154	AESULAPIUS FARMACEUTICI S.R.L.	IT
Momendol 220 mg capsule molli	not available	025829211	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
Momendol 220 mg capsule molli	not available	025829223	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
Momendol 220 mg capsule molli	not available	025829235	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
Momendol 220 mg capsule molli	not available	025829247	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
Momendol 220 mg capsule molli	not available	025829250	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
NAPROSSENE ANGELINI 220 mg compresse rivestite con film	not available	043800010	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
NAPROSSENE ANGELINI 220 mg compresse rivestite con film	not available	043800022	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
MOMENDOL 220 mg granulato per soluzione orale	not available	025829122	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
Naproxen Orion 250 mg tabletit	NL/H/3472/001	33891	AUROBINDO PHARMA (MALTA) LIMITED	FI
Naproxeno Aurobindo 250 mg comprimidos	NL/H/3472/001	80.805	LABORATORIOS AUROBINDO S.L.U.	ES
Naproxen 250mg Gastro-resistant Tablets Period Pain Reliever 250mg Gastro-resistant Tablets	not available	PL 20075/0619	ACCORD HEALTHCARE LIMITED	UK
Galpharm Period Pain Relief 250mg Gastro-Resistant Tablets	not available	PL 16028/0144	GALPHARM HEALTHCARE LIMITED	UK

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Naproxen Orion 25 mg/ml oral suspension	FI/H/879/01/DC	PL 27925/0087	ORION CORPORATION	UK
NAPROSYNE® 250 mg, comprimé	not available	34009 316 844 4 2	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 250 mg, comprimé	not available	34009 316 846 7 1	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, comprimé	not available	34009 350 241 7 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, suppositoire	not available	34009 320 505 6 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 250 mg, comprimé	not available	34009 316 843 8 1	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, suppositoire	not available	34009 320 501 0 9	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 250 mg, comprimé	not available	34009 321 767 4 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, comprimé	not available	34009 323 810 4 3	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, comprimé	not available	34009 331 389 2 9	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, comprimé	not available	34009 323 809 6 1	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 250 mg, comprimé	not available	34009 318 482 2 6	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 1000 mg, comprimé	not available	34009 334 499-3 3	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, suppositoire	not available	34009 320 502 7 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 250 mg, comprimé	not available	34009 321 766 8 7	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 250 mg, comprimé	not available	34009 316 845 0 3	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, comprimé	not available	34009 323 811 0 4	LABORATOIRES GRÜNENTHAL S.A.S.	FR
NAPROSYNE® 500 mg, suppositoire	not available	34009 320 503 3 8	LABORATOIRES GRÜNENTHAL S.A.S.	FR

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NAPROSYNE® 250 mg, comprimé	not available	34009 318 481 6 5	LABORATOIRES GRÜNENTHAL S.A.S.	FR
Naproxen Tablets BP 500mg	not available	PL 21880/0111	MEDREICH PLC	UK
Napren-E 250 mg enterotabletter	not available	6998	TAKEDA AS	NO
Napren-E 375 mg enterotabletter	not available	95-1154	TAKEDA AS	NO
Napren-E 500 mg enterotabletter	not available	6999	TAKEDA AS	NO
Naprostad 250 mg Filmtabletten	not available	904.01.01	STADA ARZNEIMITTEL AG	DE
Naprostad 500 mg Filmtabletten	not available	13523.00.00	STADA ARZNEIMITTEL AG	DE