



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 April 2017
EMA/2826/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ketoprofen (topical use only)

Procedure no.: PSUSA/00009205/201609



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
Fastum® Gel	not available	1-22361	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	AT
Ketospray 10% Spray zur Anwendung auf der Haut	not available	1-26223	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	AT
Fastum 2,5 % Gel	not available	BE155145	S.A. MENARINI BENELUX N.V.	BE
Fastum 2,5 % Gel	not available	BE155145	S.A. MENARINI BENELUX N.V.	BE
Fastum 2,5 % Gel	not available	BE219046	S.A. MENARINI BENELUX N.V.	BE
Fastum 2,5 % Gel	not available	BE219046	S.A. MENARINI BENELUX N.V.	BE
Fastum 2,5 % Gel	not available	BE155145	S.A. MENARINI BENELUX N.V.	BE
Fastum 2,5 % Gel	not available	BE219046	S.A. MENARINI BENELUX N.V.	BE
Фастум гел 2,5 % гел	not available	9700038	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	BG
Фастум гел 2,5 % гел	not available	9700038	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	BG
КЕТУМ 2,5% гел	not available	20010427	SOPHARMA AD	BG
КЕТОСПРЕЙ 10% спрей за кожа, разтвор	not available	20090332	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	BG
Топогел 2,5% гел	not available	20050477	ACTAVIS EAD	BG
Fastum 2.5% Gel	not available	13370	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	CY
Fastum 2.5% Gel	not available	13370	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	CY
FASTUM gel 25 mg/g (2.5%), gel	not available	29/658/96-C	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	CZ

Ketonal 5% krém	not available	29/938/94-C	LEK PHARMACEUTICALS D.D. LJUBLJANA	CZ
Keplat 20 mg léčivá náplast	IT/H/120/001	29/084/06-C	HISAMITSU UK LIMITED	CZ
Keplat 20 mg léčivá náplast	IT/H/120/001	29/084/06-C	HISAMITSU UK LIMITED	CZ
PRONTOFLEX 10% Kožní sprej, roztok, 10%	not available	29/228/05-C	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	CZ
Phardol Ketoprofen Schmerzgel	not available	13184.00.00	CHEMISCHE FABRIK KREUSSLER & CO. GMBH	DE
Effekton Gel mit Ketoprofen	not available	36911.00.00	TEOFARMA S.R.L.	DE
Fastum Gel, gel	not available	17810	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	DK
Fastum, 2,5% geel	not available	192998	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	EE
Begsan 25 mg/g geel	not available	612208	GRINDEKS	EE
PRONTOFLEX, 20 mg/annuses nahasprei, lahus	not available	594508	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	EE
Fastum 25 mg /g gel	not available	56.387	LABORATORIOS MENARINI, S.A.	ES
EXTRAPLUS 25 mg/g Gel	not available	58.552	PIERRE FABRE IBERICA / SPAIN	ES
ORUDIS 2,5 % GEELI	not available	12146	SANOFI OY	FI
ORUDIS 2,5 % GEELI	not available	12146	SANOFI OY	FI
ORUDIS 2,5 % GEELI	not available	12146	SANOFI OY	FI
ORUDIS 2,5 % GEELI	not available	12146	SANOFI OY	FI
KETOPROFENE SANDOZ 2,5 %, gel	not available	367 641-3	SANDOZ	FR
KETOPROFENE SANDOZ 2,5 %, gel	not available	366 186-0	SANDOZ	FR

KETOPROFENE SANDOZ 2,5 %, gel	not available	366 187-7	SANDOZ	FR
KÉTOPROFÈNE BGR 2,5%, gel	not available	3400937992978	BIOGARAN	FR
KETUM 2,5 POUR CENT, gel	not available	34009 335 836 3 7	MENARINI FRANCE	FR
KETUM 2,5 POUR CENT, gel	not available	34009 344 447 6 0	MENARINI FRANCE	FR
KETUM 2,5 POUR CENT, gel	not available	34009 344 444 7 0	MENARINI FRANCE	FR
KETUM 2,5 POUR CENT, gel	not available	34009 344 445 3 1	MENARINI FRANCE	FR
KETUM 2,5 POUR CENT, gel	not available	34009 333 549 7 8	MENARINI FRANCE	FR
KETUM 2,5 POUR CENT, gel	not available	34009 333 550 5 0	MENARINI FRANCE	FR
KETOPROFENE ARROW 2,5 %, gel	not available	NL27080	ARROW GENERIQUES	FR
KETOPROFENE TEVA SANTE 2,5 %, gel	not available	NL35329	TEVA SANTÉ	FR
KETOPROFENE EG 2,5 %, gel	not available	NL28097	EG LABO - LABORATOIRES EUROGENERICS	FR
KETOPROFENE TEVA 2,5 %, gel	not available	NL24426	TEVA SANTÉ	FR
KÉTOPROFÈNE BIOGARAN® 2,5%, gel	not available	3400935302014	BIOGARAN	FR
SOLU-KET® 1,6% Διάλυμα για στοματικές πλύσεις	not available	21345/21-9-2007	ARRIANI PHARMACEUTICALS S.A.	GR
DRASTIREL® Κρέμα εξωτερικής χρήσης 2.5%	not available	39482/02.05.2014	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.	GR
JOMEZAL 1.6% Διάλυμα για στοματικές πλύσεις	not available	101875	CROSS PHARMACEUTICALS LTD	GR
Ketonal 25 mg/g gel	NOT APPLICABLE	UP/I-530-09/11-02/332	SANDOZ D.O.O.	HR
Fastum 2,5% Gel	not available	UP/I-530-09/11-02/664	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	HR

Ketospray 100 mg/g sprej za kožu, otopina	not available	UP/I-530-09/13-02/119	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	HR
Fastum 25 mg/g gél	not available	OGYI-T-5670/04	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	HU
Fastum 25 mg/g gél	not available	OGYI-T-5670/05	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	HU
Fastum 25 mg/g gél	not available	OGYI-T-5670/01	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	HU
Fastum 25 mg/g gél	not available	OGYI-T-5670/02	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	HU
Fastum 25 mg/g gél	not available	OGYI-T-5670/03	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	HU
Keplat 20 mg gyógyszeres tapasz	IT/H/120/001	OGYI-T-10271/03	HISAMITSU UK LIMITED	HU
Keplat 20 mg gyógyszeres tapasz	IT/H/0120/001	OGYI-T-10271/02	HISAMITSU UK LIMITED	HU
Keplat 20 mg gyógyszeres tapasz	IT/H/120/001	OGYI-T-10271/01	HISAMITSU UK LIMITED	HU
Fastum 2.5% w/w Gel	not available	PA 512/1/1	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IE
ORUDIS	not available	023183130	SANOFI SPA	IT
ORUDIS	not available	023183142	SANOFI SPA	IT
LIOTONDOL 2,5% GEL	not available	036929014	SANOFI SPA	IT
KELIS GOLA 0,16% spray per mucosa orale	not available	041843020	EPIFARMA S.R.L.	IT
Kelis gola 1,6% collutorio	not available	041843018	EPIFARMA S.R.L.	IT
FLEXEN 2,5% Gel	not available	023401084	ITALFARMACO S.P.A	IT
FLEXEN 5% Gel	not available	023401122	ITALFARMACO S.P.A	IT

KELIS GOLA 0,16% spray per mucosa orale	not available	041843020	EPIFARMA S.R.L.	IT
Kelis gola 1,6% collutorio	not available	041843018	EPIFARMA S.R.L.	IT
LISACTIV GOLA 0,16% spray per mucosa orale	not available	041845025	IPSO PHARMA S.R.L.	IT
Lisactiv gola 1,6% collutorio	not available	041845013	IPSO PHARMA S.R.L.	IT
OKi infiammazione e dolore 1,6% collutorio	not available	041797010	DOMPÉ FARMACEUTICI S.P.A.	IT
OKi infiammazione e dolore 0,16% spray per mucosa orale	not available	041797022	DOMPÉ FARMACEUTICI S.P.A.	IT
ARTROSILENE 15% schiuma cutanea	not available	024022143	DOMPÉ FARMACEUTICI S.P.A.	IT
Artrosilene 5% gel	not available	024022117	DOMPÉ FARMACEUTICI S.P.A.	IT
FASTUM 2,5% GEL	not available	023417037	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
FASTUM 2,5% GEL	not available	023417114	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Fastum 2,5% spray cutaneo soluzione	not available	023417126	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Rofixdol infiammazione e dolore 1,6% collutorio	not available	041874013	POOL-PHARMA S.R.L.	IT
ROFIXDOL INFIAMMAZIONE E DOLORE 0,16% spray per mucosa orale	not available	041874025	POOL-PHARMA S.R.L.	IT
IBIFEN 50mg/g Gel	not available	024994105	IBI G. LORENZINI SPA	IT
Ketoprofene Almus 5% gel	not available	036469029	ALMUS S.R.L.	IT
OROCHET 0,16% spray per mucosa orale	not available	041842028	FG S.R.L.	IT
Orochet 1,6% collutorio	not available	041842016	FG S.R.L.	IT

ORALCARE 0,16% spray per mucosa orale	not available	041844022	PHARMEG S.R.L.	IT
Oralcare 1,6% collutorio	not available	041844010	PHARMEG S.R.L.	IT
YERASEL 10% spray cutaneo, soluzione	not available	037817018	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	IT
OROCHET 0,16% spray per mucosa orale	not available	041842028	FG S.R.L.	IT
Orochet 1,6% collutorio	not available	041842016	FG S.R.L.	IT
Ketoprofene Eurogenerici 5% gel	not available	036468027	EG SPA	IT
KETOPROFENE FARMAPRO 2,5% gel	not available	029286010	FARMAPRO S.R.L.	IT
KETOPROFENE PHARMENTIS 5% gel	not available	033713037	FARMAPRO S.R.L.	IT
Keplat 20 mg cerotto medicato	IT/H/0120/001	035641012	HISAMITSU UK LIMITED	IT
Keplat 20 mg cerotto medicato	IT/H/0120/001	035641024	HISAMITSU UK LIMITED	IT
Fastum 2,5% gelis	not available	LT/1/94/0434/004	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Fastum 2,5% gelis	not available	LT/1/94/0434/001	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Fastum 2,5% gelis	not available	LT/1/94/0434/002	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Fastum 2,5% gelis	not available	LT/1/94/0434/003	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Fastum 2,5% gelis	not available	LT/1/94/0434/005	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Begsan 25 mg/g gelis	not available	LT/1/10/2283/001	GRINDEKS	LT
Begsan 25 mg/g gelis	not available	LT/1/10/2283/002	GRINDEKS	LT

KETOPROFEN SOPHARMA 25 mg/g gels	not available	LT/1/11/2467/001	SOPHARMA AD	LT
Fastum® 2,5% gels	not available	96-0244	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LV
Begsan® 25 mg/g gels	not available	10-0012	GRINDEKS	LV
Ketoprofen Sopharma 25 mg/g gels	not available	10-0550	BRIZ LTD	LV
OKi 1,6% mouthwash	not available	MA118/00301	DOMPÉ FARMACEUTICI S.P.A.	MT
ARTROSILENE 15% cutaneous foam	not available	MA118/00102	DOMPÉ FARMACEUTICI S.P.A.	MT
ARTROSILENE 5% gel	not available	MA118/00101	DOMPÉ FARMACEUTICI S.P.A.	MT
FASTUM 2.5% GEL	not available	MA 205/00101	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	MT
FASTUM 2.5% GEL	not available	MA 205/00102	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	MT
ORUDIS 2,5 % GEL	not available	96-1460	SANOFI-AVENTIS NORGE AS	NO
ORUDIS 2,5 % GEL	not available	96-1460	SANOFI-AVENTIS NORGE AS	NO
Ketonal, 25 mg/g (2,5%), žel	not available	10858	SANDOZ GMBH	PL
Ketoprofen LGO, 25 mg/g, žel	not available	17974	LABORATORIUM GALENOWE OLSZTYN SP. Z O.O.	PL
Ketoprofen LGO, 25 mg/g, žel	not available	17974	LABORATORIUM GALENOWE OLSZTYN SP. Z O.O.	PL
Ketoprofen LGO, 25 mg/g, žel	not available	17974	LABORATORIUM GALENOWE OLSZTYN SP. Z O.O.	PL
Ketoprofen LGO, 25 mg/g, žel	not available	17974	LABORATORIUM GALENOWE OLSZTYN SP. Z O.O.	PL
OPOKAN-KETO , 25 mg/g, žel	not available	18439	AFLOFARM FARMACJA POLSKA SP. Z O.O.	PL
Ketoprofenum Fastum 25 mg/g Žel	not available	R/7472	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	PL

Ketoprofen Ziaja, 25 mg/g, żel	not available	22691	ZIAJA LTD ZAKŁAD PRODUKCJI LEKÓW SP Z O.O.	PL
Ketospray Forte, 100 mg/g, aerozol na skórę, roztwór	not available	12504	ANGELINI PHARMA POLSKA SP. Z O.O.	PL
ULTRAFASTIN, 25 mg (2,5%) żel	not available	4923	MEDANA PHARMA SPOLKA AKCYJNA	PL
Fastum 25 mg/g gel	not available	5034350	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Fastum 25 mg/g gel	not available	2212686	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Fastum 25 mg/g gel	not available	5034343	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Fastum 25 mg/g gel	not available	5026042	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Keplat, 20 mg, emplastro medicamentoso	IT/H/120/001	5421185	HISAMITSU UK LIMITED	PT
Keplat, 20 mg, emplastro medicamentoso	IT/H/120/001	5427729	HISAMITSU UK LIMITED	PT
KETONAL 25 mg/g gel	not available	4839/2004/01-02-03	LEK PHARMACEUTICALS D.D. LJUBLJANA	RO
KETONAL 25 mg/g gel	not available	4839/2004/01-02-03	LEK PHARMACEUTICALS D.D. LJUBLJANA	RO
KETONAL 25 mg/g gel	not available	4839/2004/01-02-03	LEK PHARMACEUTICALS D.D. LJUBLJANA	RO
Fastum Gel 25 mg/g gel	not available	8884/2016/03	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	RO
Fastum Gel 25 mg/g gel	not available	8884/2016/05	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	RO
Fastum Gel 25 mg/g gel	not available	8884/2016/02	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	RO
Fastum Gel 25 mg/g gel	not available	8884/2016/01	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	RO

Fastum Gel 25 mg/g gel	not available	8884/2016/04	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	RO
KETOSpray 100 mg/ g spray cutanat soluție	not available	6369/2006/01-02	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	RO
KETOPROFEN OZONE 25 mg/g gel	not available	5770/2013/01	SLAVIA PHARM SRL	RO
KETOPROFEN SLAVIA 25mg/g GEL	not available	7702/2015/01	SLAVIA PHARM SRL	RO
KETOPROFEN TIS 25 mg/g gel	not available	5661/2013/01	TIS FARMACEUTIC SA	RO
ORUDIS 2,5 % GEL	SE/H/0120/001	12402	SANOFI AB	SE
Siduro 2,5 % gel	not available	14912	MEDA AB	SE
KETONAL 25 mg/g gel	NP/H/0501/001	H/98/00840/001 (100 G)	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
KETONAL 25 mg/g gel	NP/H/0501/001	H/98/00840/002 (50 G)	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Ketonal 50 mg/g krema	not available	H/98/00840/003	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Ketonal 50 mg/g krema	not available	H/98/00840/004	LEK PHARMACEUTICALS D.D. LJUBLJANA	SI
Fastum 25 mg/g gel	not available	H/09/00603/001	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	SI
Fastum 25 mg/g gel	not available	H/09/00603/002	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	SI
Fastum 25 mg/g gel	not available	H/09/00603/003	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	SI
Prontoflex 100 mg/g dermalno pršilo, raztopina	not available	5363-I-498/14	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	SI
Ketonal 2,5 % gél	not available	29/0105/04-S	SANDOZ PHARMACEUTICALS D.D.	SK
Fastum gel	not available	29/0457/96-S	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	SK

KETOSPRAY 10 %	not available	29/0210/06-S	CYATHUS EXQUIRERE PHARMAFORSCHUNGSGMBH	SK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
ORUVAIL GEL 2.5%	not available	PL 04425/0627	AVENTIS PHARMA LTD	UK
Fastum 2.5% gel	not available	PL 10649/0006	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	UK
POWERGEL 2.5% gel	not available	PL 10649/0001	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	UK
Ketoprofen 2.5% w/w Gel	not available	PL 04917/0069	PINEWOOD LABORATORIES LIMITED	UK
Tiloket 2.5% Gel	not available	PL 11311/0127	TILLOMED LABORATORIES LTD	UK