



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

05 September 2019
EMA/529917/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ketoprofen (topical use only)

Procedure no.: PSUSA/00009205/201901

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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
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
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
OKi infiammazione e dolore 1,6% collutorio	not available	041797010	DOMPÉ FARMACEUTICI S.P.A.	IT
OKi 1,6% mouthwash	not available	MA118/00301	DOMPÉ FARMACEUTICI S.P.A.	MT

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
ARTROSILENE 15% cutaneous foam	not available	MA 118/00102	DOMPÉ FARMACEUTICI S.P.A.	MT
ARTROSILENE 5% gel	not available	MA118/00101	DOMPÉ FARMACEUTICI S.P.A.	MT
Phardol Ketoprofen Schmerzgel	not available	13184.00.00	CHEMISCHE FABRIK KREUSSLER & CO. GMBH	DE
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
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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
Tiloket 2.5% Gel	not available	PL 11311/0127	TILLOMED LABORATORIES LTD	UK
FLEXEN 2,5 g/100 g Gel	not available	023401084	ITALFARMACO S.P.A	IT
FLEXEN 5 g/100 g Gel	not available	023401122	ITALFARMACO S.P.A	IT
SOLU-KET® 1,6% Διάλυμα για στοματικές πλύσεις	not available	21345/21-9-2007	ARRIANI PHARMACEUTICALS S.A.	GR
Ketoprofene sale di lisina Zentiva 0,16% spray per mucosa orale.	not available	041844022	ZENTIVA ITALIA SRL	IT

Keplat 20 mg gyógyszeres tapasz	IT/H/0120/001	OGYI-T-10271/03	HISAMITSU UK LIMITED	HU
Keplat 20 mg cerotto medicato.	IT/H/0120/001	035641012	HISAMITSU ITALIA S.R.L.	IT
Keplat, 20 mg, emplastro medicamentoso.	IT/H/0120/001	5421185	HISAMITSU UK LIMITED	PT
Keplat 20 mg léčivá náplast	IT/H/0120/001	29/084/06-C	HISAMITSU ITALIA S.R.L.	CZ
Keplat 20 mg gyógyszeres tapasz	IT/H/0120/001	OGYI-T-10271/02	HISAMITSU UK LIMITED	HU
Keplat 20 mg gyógyszeres tapasz	IT/H/0120/001	OGYI-T-10271/01	HISAMITSU UK LIMITED	HU
Keplat 20 mg léčivá náplast	IT/H/0120/001	29/084/06-C	HISAMITSU ITALIA S.R.L.	CZ

Keplat 20 mg cerotto medicato.	IT/H/0120/001	035641024	HISAMITSU ITALIA S.R.L.	IT
Keplat, 20 mg, emplastro medicamentoso.	IT/H/0120/001	5427729	HISAMITSU UK LIMITED	PT
ORUDIS	not available	023183130	SANOFI SPA	IT
ORUDIS	not available	023183142	SANOFI SPA	IT
Ketoprofene sale di lisina Zentiva 1,6% collutorio.	not available	041844010	ZENTIVA ITALIA SRL	IT
KETOPROFENE SANDOZ 50 mg/g crema	not available	025149055	SANDOZ S.P.A.	IT
FLEXEN 2,5 g/100 g Gel	not available	023401084	ITALFARMACO S.P.A	IT

FLEXEN 5 g/100 g Gel	not available	023401122	ITALFARMACO S.P.A	IT
Effekton Gel mit Ketoprofen	not available	36911.00.00	TEOFARMA S.R.L.	DE
SOLKET infiammazione e dolore 1,6% collutorio	not available	041845013	AESCVLAPIVS FARMACEVTICI S.R.L.	IT
SOLKET infiammazione e dolore 0,16% spray per mucosa orale	not available	041845025	AESCVLAPIVS FARMACEVTICI S.R.L.	IT
IBIFEN 50 mg/g Gel	not available	024994105	IBI G. LORENZINI SPA	IT
Orudis 2,5 % geeli	not available	12146	SANOVI OY	FI
Orudis 2,5 % geeli	not available	12146	SANOVI 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 % gel	not available	96/1460	SANOFI-AVENTIS NORGE AS	NO
Orudis® 2,5 % gel	not available	96/1460	SANOFI-AVENTIS NORGE AS	NO
Orudis 2,5 % gel	SE/H/0120/001	12402	SANOFI AB	SE
Orudis 2,5 % geeli	not available	12146	SANOFI OY	FI
Fastum 2,5 % Gel	not available	BE155145	MENARINI BENELUX N.V./S.A.	BE

Fastum 2,5 % Gel	not available	BE155145	MENARINI BENELUX N.V./S.A.	BE
Fastum 2,5 % Gel	not available	BE219046	MENARINI BENELUX N.V./S.A.	BE
Fastum 2,5 % Gel	not available	BE219046	MENARINI BENELUX N.V./S.A.	BE
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
Fastum 25 mg/g gelis	not available	LT/1/94/0434/004	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Fastum 25 mg/g gelis	not available	LT/1/94/0434/001	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Fastum 25 mg/g gelis	not available	LT/1/94/0434/002	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
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
Fastum 25 mg/g gél	not available	OGYI-T-5670/04	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	HU

Fastum 25 mg/g gelis	not available	LT/1/94/0434/003	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
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
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 gel 25 mg/g, dermálny gél	not available	29/0457/96-S	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	SK
Fastum 25 mg/g gel	not available	H/09/00603/003	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	SI

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
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
Fastum 25 mg/g gelis	not available	LT/1/94/0434/005	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT

Fastum 25 mg/g gél	not available	OGYI-T-5670/05	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	HU
Fastum 2.5% Gel	not available	MA205/00101	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	MT
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
Fastum 2.5% Gel	not available	MA205/00102	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	MT
Fastum® 2,5% gels	not available	96-0244	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LV

Fastum 2,5 % Gel	not available	2011041086	MENARINI BENELUX N.V./S.A.	LU
Fastum 2,5 % Gel	not available	2011041086	MENARINI BENELUX N.V./S.A.	LU
FASTUM 25 mg/g GEL.	not available	023417037	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Fastum 2.5% w/w Gel	not available	PA 512/1/1	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IE
FASTUM 25 mg/g GEL	not available	023417114	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Fastum, 2,5% geel	not available	192998	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	EE
FASTUM 2.5% GEL	not available	13370	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	CY

FASTUM 25 mg/g spray cutaneo, soluzione	not available	023417126	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Fastum® Gel	not available	1-22361	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	AT
Fastum 2,5 % Gel	not available	BE155145	MENARINI BENELUX N.V./S.A.	BE
Fastum 2,5 % Gel	not available	BE219046	MENARINI BENELUX N.V./S.A.	BE
Fastum 25 mg /g gel	not available	56.387	LABORATORIOS MENARINI, S.A.	ES
FASTUM 2.5% GEL	not available	13370	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	CY
FASTUM gel 25 mg/g, gel	not available	29/658/96-C	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	CZ