



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 October 2022
EMA/CMDh/890125/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): ketoprofen (topical use only)

Procedure No. PSUSA/00009205/202201



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
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
Effekton Gel mit Ketoprofen	not available	36911.00.00	TEOFARMA S.R.L.	DE
Euspidol Gola 0,16% spray per mucosa orale.	not available	041844022	ZENTIVA ITALIA S.R.L.	IT
Euspidol Gola 1,6% collutorio.	not available	041844010	ZENTIVA ITALIA S.R.L.	IT
Euspidol Gola 1,6% collutorio.	not available	041844010	ZENTIVA ITALIA S.R.L.	IT
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 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	2011041086	MENARINI BENELUX N.V./S.A.	LU
Fastum 2,5 % Gel	not available	2011041086	MENARINI BENELUX N.V./S.A.	LU
Fastum 2,5% gels	not available	96-0244	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LV
FASTUM 2.5% GEL	not available	13370	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	CY
FASTUM 2.5% GEL	not available	MA 205/00101	A. MENARINI - INDUSTRIE	MT

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			FARMACEUTICHE RIUNITE - S.R.L.	
FASTUM 2.5% GEL	not available	MA 205/00102	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	MT
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	56.387	LABORATORIOS MENARINI, S.A.	ES
FASTUM 25 mg/g gel	not available	29/658/96-C	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	CZ
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-5670/01	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 25 mg/g GEL.	not available	023417037	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
FASTUM 25 mg/g GEL.	not available	023417114	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
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	LT

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			FARMACEUTICHE RIUNITE - S.R.L.	
Fastum 25 mg/g gelis	not available	LT/1/94/0434/003	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Fastum 25 mg/g gelis	not available	LT/1/94/0434/005	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	LT
Fastum Gel	not available	1-22361	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	AT
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 gel 25 mg/g, dermálny gél	not available	29/0457/96-S	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	SK
Fastum, 2,5% geel	not available	192998	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	EE
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
IBIFEN 50 mg/g Gel	not available	024994105	IBI G. LORENZINI SPA	IT
ILMOCIN GOLA DOLORE 0,16% spray per mucosa orale.	not available	041842028	FARMITALIA S.R.L.	IT

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ILMOCIN GOLA DOLORE 1,6% collutorio	not available	041842016	FARMITALIA S.R.L.	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
Keplat 20 mg cerotto medicato.	not available	035641012	HISAMITSU ITALIA S.R.L.	IT
Keplat 20 mg cerotto medicato.	IT/H/0120/001	035641024	HISAMITSU ITALIA S.R.L.	IT
Keplat 20 mg gyógyszeres tapasz	IT/H/0120/001	OGYI-T-10271/03	HISAMITSU ITALIA S.R.L.	HU
Keplat 20 mg gyógyszeres tapasz	IT/H/0120/001	OGYI-T-10271/02	HISAMITSU ITALIA S.R.L.	HU
Keplat 20 mg gyógyszeres tapasz	IT/H/0120/001	OGYI-T-10271/01	HISAMITSU ITALIA S.R.L.	HU
Keplat 20 mg léčivá náplast	IT/H/0120/001	29/084/06-C	HISAMITSU ITALIA S.R.L.	CZ
Keplat 20 mg léčivá náplast	IT/H/0120/001	29/084/06-C	HISAMITSU ITALIA S.R.L.	CZ
Keplat 20 mg léčivá náplast	IT/H/0120/001	29/084/06-C	HISAMITSU ITALIA S.R.L.	CZ
Keplat, 20 mg, emplastro medicamentoso.	IT/H/0120/001	5421185	HISAMITSU ITALIA S.R.L.	PT
Keplat, 20 mg, emplastro medicamentoso.	IT/H/0120/001	5581137	HISAMITSU ITALIA S.R.L.	PT
Keplat, 20 mg, emplastro medicamentoso.	IT/H/0120/001	5427729	HISAMITSU ITALIA S.R.L.	PT
KETOPROFENE SANDOZ 50 mg/g crema	not available	025149055	SANDOZ S.P.A.	IT
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,	not available	34009 344 444 7 0	MENARINI FRANCE	FR

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gel				
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
OKi gola 0,16% spray per mucosa orale	not available	041797022	DOMPÉ FARMACEUTICI S.P.A.	IT
OKi gola 1,6% collutorio	not available	041797010	DOMPÉ FARMACEUTICI S.P.A.	IT
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
Orudis 2,5 % geeli	not available	12146	SANOFI OY	FI
Orudis 2,5 % gel	not available	12146	SANOFI OY	FI
Orudis 2,5 % gel	not available	12146	SANOFI OY	FI
Orudis 2,5 % gel	not available	12146	SANOFI OY	FI
Orudis 2,5 % gel	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 5% gel	not available	023183142	SANOFI S.R.L.	IT
Phardol Ketoprofen Schmerzgel	not available	13184.00.00	CHEMISCHE FABRIK KREUSSLER & CO. GMBH	DE
POWERGEL 2.5% gel	not available	PL 10649/0001	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	XI
ROFIXDOL INFIAMMAZIONE E DOLORE 0,16% spray per mucosa orale.	not available	041874025	POOL-PHARMA S.R.L.	IT
Rofixdol infiammazione e dolore 1,6% collutorio.	not available	041874013	POOL-PHARMA S.R.L.	IT
SOLKET infiammazione e	not available	041845025	AESCLAPIUS	IT

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dolore 0,16% spray per mucosa orale.			FARMACEUTICI S.R.L.	
SOLKET infiammazione e dolore 1,6% collutorio.	not available	041845013	AESULAPIUS FARMACEUTICI S.R.L.	IT
SOLKET infiammazione e dolore 1,6% collutorio.	not available	041845013	AESULAPIUS FARMACEUTICI S.R.L.	IT
SOLU-KET® 1,6% Διάλυμα για στοματικές πλύσεις	not available	21345/21-9-2007	ARRIANI PHARMACEUTICALS S.A.	GR
Tiloket 2.5% Gel	not available	PL 11311/0127	TILLOMED LABORATORIES LTD	XI