



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2016
EMA/345763/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ketoprofen (topical use only)

Procedure no.: PSUSA/00009205/201509



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		024022117	Dompé Farmaceutici S.P.A.	Italy
Artrosilene		024022143	Dompé Farmaceutici S.P.A.	Italy
Artrosilene		MA118/00101	Dompé Farmaceutici S.P.A.	Malta
Artrosilene		MA118/00102	Dompé Farmaceutici S.P.A.	Malta
Begsan		612208	Grindeks	Estonia
Begsan		10-0012	Grindeks	Latvia
Begsan		LT/1/10/2283/001 \$ LT/1/10/2283/002	Grindeks	Lithuania
Drastirel		39482/02.05.2014	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Extraplus		58 552	Pierre Fabre Iberica / Spain	Spain
Fastum		1-22361	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Austria
Fastum		BE155145 \$ BE219046	S.A. Menarini Benelux N.V.	Belgium
Fastum		UP/I-530-09/11-02/664	Berlin-Chemie Menarini Hrvatska D.O.O.	Croatia
Fastum		13370	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Cyprus
Fastum		29/658/96-C	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Czech Republic
Fastum		17810	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Denmark
Fastum		192998	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Estonia
Fastum		OGYI-T-5670/01 \$ OGYI-	A. Menarini - Industrie	Hungary

		T-5670/02 \$ OGYI-T-5670/04	Farmaceutiche Riunite - S.R.L.	
Fastum		OGYI-T-5670/03 \$ OGYI-T-5670/05	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Hungary
Fastum		PA 512/1/1	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Ireland
Fastum		023417037 \$ 023417114	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Italy
Fastum		023417126	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Italy
Fastum		96-0244	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Latvia
Fastum		LT/1/94/0434/001 \$ LT/1/94/0434/005	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Lithuania
Fastum		LT/1/94/0434/002 \$ LT/1/94/0434/003 \$ LT/1/94/0434/004	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Lithuania
Fastum		0115/11041086	S.A. Menarini Benelux N.V.	Luxembourg
Fastum		MA205/00101	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Malta
Fastum		MA205/00102	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Malta
Fastum		R/7472	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Poland
Fastum		2212686 \$ 5026042 \$ 5034343 \$ 5034350	A. Menarini Portugal, Farmacêutica, S.A.	Portugal
Fastum		29/0457/96-S	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Slovakia

Fastum		H/09/00603/001 \$ H/09/00603/002 \$ H/09/00603/003	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Slovenia
Fastum		56.387	Laboratorios Menarini, S.A.	Spain
Fastum Gel		6698/2006/01 \$ 6698/2006/02 \$ 6698/2006/03 \$ 6698/2006/04	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Romania
Fastum Gel		6698/2006/05	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Romania
Flexen		023401084 \$ 023401122	Italfarmaco S.P.A	Italy
Ibifen		024994105	Ibi G. Lorenzini Spa	Italy
Ibifen		024994218	Ibi G. Lorenzini Spa	Italy
Jomezal		101875/28-11-2014	Cross Pharmaceuticals Ltd	Greece
Kelis Gola		041843018	Epifarma S.R.L.	Italy
Kelis Gola		041843020	Epifarma S.R.L.	Italy
Keplat	IT/H/0120/001	29/084/06-C	Hisamitsu UK Limited	Czech Republic
Keplat		OGYI-T-10271/01 - 02	Hisamitsu UK Limited	Hungary
Keplat	IT/H/0120	035641012 \$ 035641024	Hisamitsu UK Limited	Italy
Keplat		5421185 \$ 5427729 \$ 5581137	Hisamitsu UK Limited	Portugal
Ketofarm		036466023	Ibsa Farmaceutici Italia	Italy
Ketonal		UP/I-530-09/11-02/332	Sandoz D.O.O.	Croatia
Ketonal		29/938/94-C	Lek Pharmaceuticals D.D. Ljubljana	Czech Republic
Ketonal		10858	Sandoz Gmbh	Poland
Ketonal		4839/2004/01 \$ 4839/2004/02 \$ 4839/2004/03	Lek Pharmaceuticals D.D. Ljubljana	Romania
Ketonal		29/0105/04-S	Sandoz Pharmaceuticals D.D.	Slovakia
Ketonal		5363-I-154/11 \$ 5363-I-	Lek Pharmaceuticals D.D.	Slovenia

		155/11	Ljubljana	
Ketonal	NP/H/0501/001	H/98/00840/001 (100 G) \$ H/98/00840/002 (50 G)	Lek Pharmaceuticals D.D. Ljubljana	Slovenia
Ketoprofen Lgo		17974	Laboratorium Galenowe Olsztyn Sp. Z O.O.	Poland
Ketoprofen Ozone		5770/2013/01	Slavia Pharm Srl	Romania
Ketoprofen Pinewood Laboratories		PL 04917/0069	Pinewood Laboratories Limited	United Kingdom
Ketoprofen Slavia		7702/2015/01	Slavia Pharm Srl	Romania
Ketoprofen Sopharma		10-0550	Briz Ltd	Latvia
Ketoprofen Sopharma		LT/1/11/2467/001	Sopharma Ad	Lithuania
Ketoprofen Tis		5661/2013/01	Tis Farmaceutic Sa	Romania
Ketopropene Almus		036469029	Almus S.R.L	Italy
Ketopropene Arrow		NL27080	Arrow Generiques	France
Kétoprofène Bgr		32779	Biogaran	France
Kétoprofène Biogaran		22490	Biogaran	France
Ketopropene Eurogenerici		036468.027	Eg Spa	Italy
Ketopropene Farmapro		029286010	Farmapro S.R.L.	Italy
Ketopropene Pharmentis		033713037	Farmapro S.R.L.	Italy
Kétoprofène Ratio		NL34415	Teva Santé	France
Kétoprofène Ratiopharm		NL28055	Teva Santé	France
Ketopropene Sandoz		366 186-0 \$ 366 187-7 \$ 367 641-3	Sandoz	France
Ketopropene Sandoz		025149055	Sandoz S.P.A.	Italy
Ketopropene Teva		NL24426	Teva Santé	France
Ketopropene Teva Sante		NL35329	Teva Santé	France
Ketores		21167	Pharmaswiss česká Republika S.R.O.	Poland
Ketospray		1-26223	Cyathus Exquirere Pharmaforschungsgmbh	Austria
Ketospray		UP/I-530-09/13-02/119	Cyathus Exquirere Pharmaforschungsgmbh	Croatia

Ketospray		6369/2006/01-02	Cyathus Exquirere Pharmaforschungsgmbh	Romania
Ketospray		29/0210/06-S	Cyathus Exquirere Pharmaforschungsgmbh	Slovakia
Ketospray Forte		12504	Angelini Pharma Polska Sp. Z O.O.	Poland
Ketum		34009 333 549 7 8 \$ 34009 333 550 5 0 \$ 34009 335 836 3 7 \$ 34009 344 444 7 0 \$ 34009 344 445 3 1 \$ 34009 344 447 6 0	Menarini France	France
Liotondol		036929014	Sanofi Spa	Italy
Lisactiv Gola		041845013	Ipsos Pharma S.R.L.	Italy
Lisactiv Gola		041845025	Ipsos Pharma S.R.L.	Italy
Oki		MA118/00301	Dompé Farmaceutici S.P.A.	Malta
Oki Infiammazione E Dolore		041797010	Dompé Farmaceutici S.P.A.	Italy
Oki Infiammazione E Dolore		041797022	Dompé Farmaceutici S.P.A.	Italy
Opokan-Keto		18439	Aflofarm Farmacja Polska Sp. Z O.O.	Poland
Oralcare		041844010	Pharmeg S.R.L.	Italy
Oralcare		041844022	Pharmeg S.R.L.	Italy
Orochet		041842016	Fg S.R.L.	Italy
Orochet		041842028	Fg S.R.L.	Italy
Orudis		12146	Sanofi Oy	Finland
Orudis		023183130 \$ 023183142	Sanofi Spa	Italy
Orudis		96-1460	Sanofi-Aventis Norge As	Norway
Orudis	SE/H/0120/001	12402	Sanofi Ab	Sweden
Oruvail		PL 04425/0627	Aventis Pharma Ltd	United Kingdom
Phardol		13184.00.00	Chemische Fabrik Kreussler & Co. Gmbh	Germany

Powergel		PL 10649/0001	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	United Kingdom
Prontoflex		29/228/05-C	Cyathus Exquirere Pharmaforschungsgmbh	Czech Republic
Prontoflex		594508	Cyathus Exquirere Pharmaforschungsgmbh	Estonia
Prontoflex		5363-I-498/14	Cyathus Exquirere Pharmaforschungsgmbh	Slovenia
Rofixdol Infiammazione E Dolore		041874013	Pool-Pharma S.R.L.	Italy
Rofixdol Infiammazione E Dolore		041874025	Pool-Pharma S.R.L.	Italy
Siduro		14912	Meda Ab	Sweden
Tiloket		PL 11311/0127	Tillomed Laboratories Ltd	United Kingdom
Ultrafastin		4923	Medana Pharma Spolka Akcyjna	Poland
Yerasel		037817018	Cyathus Exquirere Pharmaforschungsgmbh	Italy
кетоспрей		20090332	Cyathus Exquirere Pharmaforschungsgmbh	Bulgaria
кетум		20010427	Sopharma Ad	Bulgaria
топогел		20050477	Actavis Ead	Bulgaria
фастум		9700038	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Bulgaria