



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA//210015/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): ketoprofen (all formulations except topical)

Procedure No.: PSUSA/00001809/201707



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
Alrheumun®forte, 100 mg Hartkapseln	not available	2440.00.00	TEOFARMA S.R.L.	DE
Alrheumunâ, 50 mg	not available	6169911.00.00	TEOFARMA S.R.L.	DE
Valket 200 Retard	not available	PL 11311/0460	TILLOMED LABORATORIES LTD	UK
OKi 160 mg supposte	not available	028511057	DOMPÉ FARMACEUTICI S.P.A.	IT
OKi 160 mg suppositories	not available	MA118/00305	DOMPÉ FARMACEUTICI S.P.A.	MT
OKi 60 mg supposte	not available	028511071	DOMPÉ FARMACEUTICI S.P.A.	IT
OKi 60 mg suppositories	not available	MA118/00304	DOMPÉ FARMACEUTICI S.P.A.	MT
OKi 30 mg supposte	not available	028511083	DOMPÉ FARMACEUTICI S.P.A.	IT
OKi 30 mg suppositories	not available	MA118/00303	DOMPÉ FARMACEUTICI S.P.A.	MT
OKi 80 mg granulato per soluzione orale	not available	028511095	DOMPÉ FARMACEUTICI S.P.A.	IT
OKi 80 mg/ml oral drops, solution	not available	MA118/00302	DOMPÉ FARMACEUTICI S.P.A.	MT
OKi 160 mg/2 ml soluzione iniettabile per uso intramuscolare	not available	028511158	DOMPÉ FARMACEUTICI S.P.A.	IT
OKi 80 mg/ml gocce orali, soluzione	not available	028511145	DOMPÉ FARMACEUTICI S.P.A.	IT
ARTROSILENE 160 mg supposte	not available	024022030	DOMPÉ FARMACEUTICI S.P.A.	IT
ARTROSILENE 320 mg capsule rigide a rilascio prolungato	not available	024022129	DOMPÉ FARMACEUTICI S.P.A.	IT
ARTROSILENE 160 mg/2 ml soluzione iniettabile	not available	024022170	DOMPÉ FARMACEUTICI S.P.A.	IT
Tiloket 50mg Capsules	not available	PL 11311/0155	TILLOMED LABORATORIES LTD	UK
FLEXEN 100 mg polvere e solvente per soluzione iniettabile per uso intramuscolare	not available	023401108	ITALFARMACO S.P.A	IT
FLEXEN 100 mg polvere e solvente per soluzione iniettabile per uso endovenoso	not available	023401096	ITALFARMACO S.P.A	IT
FLEXEN 100 mg supposte	not available	023401058	ITALFARMACO S.P.A	IT
FLEXEN 200 mg capsule rigide a rilascio prolungato	not available	023401110	ITALFARMACO S.P.A	IT
FLEXEN 50 mg capsule molli	not available	023401021	ITALFARMACO S.P.A	IT
KETOPROFENE MACOPHARMA 100 mg, solution pour perfusion	FR/H/0469/001	34009 580 376 1 0	MACO PHARMA	FR
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	34009 580 382 1 1	MACO PHARMA	FR
KETOPROFENE MACOPHARMA 100 mg, solution pour perfusion	FR/H/0469/001	34009 419 161 7 5	MACO PHARMA	FR
KETOPROFENE MACOPHARMA 100 mg, solution pour	FR/H/0469/001	34009 419 162 3 6	MACO PHARMA	FR

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
perfusion				
KETOPROFENE MACOPHARMA 100 mg, solution pour perfusion	FR/H/0469/001	34009 580 377 8 8	MACO PHARMA	FR
KETOPROFENE MACOPHARMA 100 mg, solution pour perfusion	FR/H/0469/001	34009 419 165 2 6	MACO PHARMA	FR
KETOPROFENE MACOPHARMA 100 mg, solution pour perfusion	FR/H/0469/001	34009 419 166 9 4	MACO PHARMA	FR
KETOPROFENE MACOPHARMA 100 mg, solution pour perfusion	FR/H/0469/001	34009 580 378 4 9	MACO PHARMA	FR
KETOPROFENE MACOPHARMA 100 mg, solution pour perfusion	FR/H/0469/001	34009 580 379 0 0	MACO PHARMA	FR
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	34009 419 176 4 6	MACO PHARMA	FR
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	34009 419 177 0 7	MACO PHARMA	FR
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	34009 580 380 9 9	MACO PHARMA	FR
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	34009 580 381 5 0	MACO PHARMA	FR
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	34009 419 178 7 5	MACO PHARMA	FR
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	34009 419 179 3 6	MACO PHARMA	FR
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	34009 580 383 8 9	MACO PHARMA	FR
KETOPROFENE MACOPHARMA 100 mg, solution pour perfusion	FR/H/0469/001	1211/11060032	MACO PHARMA	LU
KETOPROFENE MACOSOL 100 mg, solution pour perfusion	FR/H/0470/001	1211/11060033	MACO PHARMA	LU
Sprintafen 25 mg filmomhulde tabletten	not available	RVG 119317	OMEGA PHARMA LTD	NL
Sprintafen 25 mg tabletti, kalvopäällysteinen	NL/H/3583/002	34225	OMEGA PHARMA LTD	FI
Ibifen 25 mg/ml gocce orali soluzione	not available	024994220	IBI G. LORENZINI SPA	IT
Ibifen 50 mg capsule rigide	not available	024994117	IBI G. LORENZINI SPA	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
Ibifen 200 mg compresse a rilascio prolungato	not available	024994168	IBI G. LORENZINI SPA	IT
Ibifen 100 mg capsule rigide	not available	024994081	IBI G. LORENZINI SPA	IT
Ibifen 50 mg granulato effervescente	not available	024994170	IBI G. LORENZINI SPA	IT
Ibifen 100 mg/2,5 ml soluzione iniettabile per uso intramuscolare	not available	024994182	IBI G. LORENZINI SPA	IT
Ibifen 100 mg/5 ml soluzione iniettabile per uso endovenoso	not available	024994194	IBI G. LORENZINI SPA	IT
KETOPROFENE RANBAXY 100 mg, comprimé pelliculé	not available	NL 21351	RANBAXY PHARMACIE GENERIQUES	FR
KETOPROFENE RANBAXY 50 mg, gélule	not available	NL 21410	RANBAXY PHARMACIE GENERIQUES	FR
FASTUM®	not available	54.445	LABORATORIOS MENARINI, S.A.	ES
KETOPROFENE MEDAC 100 mg/4 ml, solution à diluer pour perfusion	not available	6 783 452 1	MEDAC SAS	FR
Tiloket CR 200 mg Capsules	not available	PL 11311/0104	TILLOMED LABORATORIES LTD	UK
Tiloket CR 100 mg Capsules	not available	PL 11311/0103	TILLOMED LABORATORIES LTD	UK
Oruvail 200 mg Prolonged-Release Capsules, Hard	not available	PL 04425/0599	AVENTIS PHARMA LTD	UK
Oruvail 200 mg Prolonged-Release Capsules, Hard	not available	PL 04425/0599	AVENTIS PHARMA LTD	UK
ORUVAIL 100 MG CAPSULE	not available	PL 04425/0597	AVENTIS PHARMA LTD	UK
ORUVAIL 100 MG CAPSULE	not available	PL 04425/0597	AVENTIS PHARMA LTD	UK
ORUVAIL 100 MG CAPSULE	not available	PL 04425/0597	AVENTIS PHARMA LTD	UK
ORUDIS 50 MG KAPSELI, KOVA	not available	7441	SANOFI OY	FI
ORUDIS 100 MG KAPSELI, KOVA	not available	8644	SANOFI OY	FI
ORUDIS 100 MG KAPSELI, KOVA	not available	8644	SANOFI OY	FI
ORUDIS 100 MG KAPSELI, KOVA	not available	8644	SANOFI OY	FI
Orudis 100 mg kapsel, hård	not available	10058	SANOFI AB	SE
ORUDIS	not available	10058	SANOFI AB	SE
ORUDIS	not available	10058	SANOFI AB	SE
ORUDIS 50 MG KAPSELI, KOVA	not available	7441	SANOFI OY	FI
ORUDIS	not available	023183027	SANOFI SPA	IT
PROFENID 50 MG-KAPSELN	not available	1-15652	SANOFI-AVENTIS GMBH OSTERREICH	AT

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
PROFENID 100 MG-KAPSELN	not available	1-19745	SANOFI-AVENTIS GMBH OSTERREICH	AT
PROFENID 100 MG-KAPSELN	not available	1-19745	SANOFI-AVENTIS GMBH OSTERREICH	AT
PROFENID 50 MG-KAPSELN	not available	1-15652	SANOFI-AVENTIS GMBH OSTERREICH	AT
PROFENID 100 MG-KAPSELN	not available	1-19745	SANOFI-AVENTIS GMBH OSTERREICH	AT
Orudis 50 mg cápsulas	not available	52097	SANOFI-AVENTIS, S.A.	ES
ORUDIS	not available	023183041	SANOFI SPA	IT
ORUDIS 200 mg capsule rigide a rilascio prolungato	not available	023183193	SANOFI SPA	IT
ORUDIS	not available	023183205	SANOFI SPA	IT
ORUVAIL 200	not available	RVG 12197	SANOFI-AVENTIS NETHERLANDS B.V.	NL
ORUVAIL 200	not available	RVG 12197	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Oruvail 100, capsules met gereguleerde afgifte 100 mg	not available	RVG 12196	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Oruvail 150, capsules met gereguleerde afgifte 150 mg	not available	RVG 17667	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Oruvail 150, capsules met gereguleerde afgifte 150 mg	not available	RVG 17667	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Oruvail 100, capsules met gereguleerde afgifte 100 mg	not available	RVG 12196	SANOFI-AVENTIS NETHERLANDS B.V.	NL
Orudis 200 retard, tabletten met gereguleerde afgifte 200 mg	not available	RVG 10574	SANOFI-AVENTIS NETHERLANDS B.V.	NL
ORUDIS	not available	7816	SANOFI-AVENTIS NORGE AS	NO
ORUDIS	not available	7816	SANOFI-AVENTIS NORGE AS	NO
ORUDIS	not available	7904	SANOFI-AVENTIS NORGE AS	NO
ORUDIS	not available	7816	SANOFI-AVENTIS NORGE AS	NO
ORUDIS	not available	7904	SANOFI-AVENTIS NORGE AS	NO
Профенид LP 200 mg, таблетки с удължено освобождаване	not available	9700090	SANOFI BULGARIA EOOD	BG

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
ПРОФЕНИД 100 mg, супозитории	not available	20030008	SANOFI BULGARIA EOOD	BG
БИ-ПРОФЕНИД 150 mg таблетки с изменено освобождаване	not available	9900097	SANOFI BULGARIA EOOD	BG
PROFENID 50 MG, GÉLULE	not available	313 890-5	SANOFI-AVENTIS FRANCE	FR
TOPREC 25 mg, comprimé	not available	561 167-1	SANOFI-AVENTIS FRANCE	FR
TOPREC 25 mg, comprimé	not available	330 810-6	SANOFI-AVENTIS FRANCE	FR
PROFEMIGR 150 MG, COMPRIME SECABLE	not available	325 414-9	SANOFI-AVENTIS FRANCE	FR
PROFENID 50 MG, GÉLULE	not available	34009 499 392 0 6	SANOFI-AVENTIS FRANCE	FR
PROFENID LP 200 mg, gélule à libération prolongée	not available	331 583-3	SANOFI-AVENTIS FRANCE	FR
PROFEMIGR 150 MG, COMPRIME SECABLE	not available	558 980-7	SANOFI-AVENTIS FRANCE	FR
PROFEMIGR 150 MG, COMPRIME SECABLE	not available	362 745-5	SANOFI-AVENTIS FRANCE	FR
PROFENID LP 200 mg, comprimé enrobé à libération prolongée	not available	328 259-4	SANOFI-AVENTIS FRANCE	FR
PROFEMIGR 150 MG, COMPRIME SECABLE	not available	325 413-2	SANOFI-AVENTIS FRANCE	FR
PROFEMIGR 150 MG, COMPRIME SECABLE	not available	3400937522496	SANOFI-AVENTIS FRANCE	FR
BI-PROFENID LP 100 MG, COMPRIME SECABLE A LIBERATION PROLONGEE	not available	34009 399 803 9 3	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 MG, COMPRIMÉ PELLICULÉ	not available	557 345-6	SANOFI-AVENTIS FRANCE	FR
BI-PROFENID LP 100 MG, COMPRIME SECABLE A LIBERATION PROLONGEE	not available	34009 399 804 5 4	SANOFI-AVENTIS FRANCE	FR
KETOPROFENE ZENTIVA LP 100 MG, COMPRIME SECABLE A LIBERATION PROLONGEE	not available	34009 347 189 8 4	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 MG, SUPPOSITOIRE	not available	34009 494 171 6 2	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 MG, SUPPOSITOIRE	not available	317 929-3	SANOFI-AVENTIS FRANCE	FR
TOPREC 1 mg/ml ENFANTS ET NOURRISSONS, sirop	not available	351 573-3	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 MG, COMPRIMÉ PELLICULÉ	not available	333 020-6	SANOFI-AVENTIS FRANCE	FR
BI-PROFENID LP 100 MG, COMPRIME SECABLE A LIBERATION PROLONGEE	not available	34009 399 802 2 5	SANOFI-AVENTIS FRANCE	FR
Profenid 100 mg comprimé filmaté	not available	6448/2014/01	SANOFI ROMANIA SRL	RO
Orudis Retard 200 mg comprimidos de liberación prolongada	not available	57128	SANOFI-AVENTIS, S.A.	ES
PROFENID 100 mg/2 ml, solution injectable (I.M.)	not available	323 307-0	SANOFI-AVENTIS FRANCE	FR

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
ПРОФЕНИД 100 mg прах и разтворител за инжекционен разтвор	not available	970 0092	SANOFI BULGARIA EOOD	BG
ПРОФЕНИД 100 mg прах и разтворител за инжекционен разтвор	not available	20040127	SANOFI BULGARIA EOOD	BG
PROFENID 100 mg, poudre pour solution injectable (I.V.) en flacon	not available	557 466-8	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 mg/2 ml, solution injectable (I.M.)	not available	326 775-5	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 MG/2 ML, SOLUTION INJECTABLE (IM)	not available	560 279-0	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 MG/2 ML, SOLUTION INJECTABLE (IM)	not available	346 603-5	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 MG/2 ML, SOLUTION INJECTABLE (IM)	not available	342 921-2	SANOFI-AVENTIS FRANCE	FR
PROFENID 100 mg/2 ml, solution injectable (I.M.)	not available	554 722-3	SANOFI-AVENTIS FRANCE	FR
Oruvail 200 mg Prolonged-Release Capsules, Hard	not available	PL 04425/0599	AVENTIS PHARMA LTD	UK
ORUVAIL 100 MG CAPSULE	not available	PL 04425/0597	AVENTIS PHARMA LTD	UK
ORUVAIL 100 MG CAPSULE	not available	PL 04425/0597	AVENTIS PHARMA LTD	UK
ORUVAIL 100 MG CAPSULE	not available	PL 04425/0597	AVENTIS PHARMA LTD	UK
Oruvail 200 mg Prolonged-Release Capsules, Hard	not available	PL 04425/0599	AVENTIS PHARMA LTD	UK
ORUVAIL 100 MG CAPSULE	not available	PL 04425/0597	AVENTIS PHARMA LTD	UK
Oruvail 200 mg Prolonged-Release Capsules, Hard	not available	PL 04425/0599	AVENTIS PHARMA LTD	UK
Profenid 50 mg Konzentrat zur Infusionsbereitung	not available	1-20909	SANOFI-AVENTIS GMBH OSTERREICH	AT
Profenid retard 200 mg Kapseln	not available	1-19744	SANOFI-AVENTIS GMBH OSTERREICH	AT
Profenid 100 mg Ampullen	not available	1-19749	SANOFI-AVENTIS GMBH OSTERREICH	AT
Profenid retard 200 mg Kapseln	not available	1-19744	SANOFI-AVENTIS GMBH OSTERREICH	AT
Profenid 100 mg Ampullen	not available	1-19749	SANOFI-AVENTIS GMBH OSTERREICH	AT
ROFENID READY MIX	not available	0100748	SANOFI BELGIUM	LU
ROFENID 200 LONG ACTING	not available	0006/09050337	SANOFI BELGIUM	LU
Birofenid 150 mg, comprimés à libération modifiée	not available	0006/09050335	SANOFI BELGIUM	LU
ROFENID 200 LONG ACTING	not available	0006/09050337	SANOFI BELGIUM	LU

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PROFENID	not available	R/0985	SANOFI-AVENTIS FRANCE	PL
BI-PROFENID	not available	4121	SANOFI-AVENTIS FRANCE	PL
Profenid, 100 mg, tabletki powlekane	not available	7607	SANOFI-AVENTIS FRANCE	PL
BI-PROFENID	not available	4121	SANOFI-AVENTIS FRANCE	PL
PROFENID	not available	7904	SANOFI-AVENTIS FRANCE	PL
Oruvail 200mg Prolonged-Release Capsules, Hard	not available	PA 540/119/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Oruvail 200mg Prolonged-Release Capsules, Hard	not available	PA 540/119/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Orudis Retard 200 mg depotkapsel, hård	not available	11583	SANOFI AB	SE
Orudis Retard 200 mg depotkapsel, hård	not available	11583	SANOFI AB	SE
PROFENID 100 mg cápsulas	not available	5470497	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
PROFENID 100 mg cápsulas	not available	9396234	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Orudis 100 mg hörð forðahylki	not available	930030	SANOFI-AVENTIS NORGE AS	IS
Birofenid 150 mg, tabletten met gereguleerde afgifte	not available	BE148066	SANOFI BELGIUM	BE
PROFENID 100 mg/2 ml solução injectável	not available	9424036	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Rofenid Long Acting 200 mg, harde capsules met verlengde afgifte	not available	BE140095	SANOFI BELGIUM	BE
Oruvail 150 mg Prolonged-Release Capsules, Hard	not available	PL 04425/0598	AVENTIS PHARMA LTD	UK
PROFENID 100 mg cápsulas	not available	4630190	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Rofenid Ready Mix I.M. 100 mg, oplossing voor injectie	not available	BE132063	SANOFI BELGIUM	BE
Oruvail 150 mg Prolonged-Release Capsules, Hard	not available	PL 04425/0598	AVENTIS PHARMA LTD	UK
PROFENID RETARD 200 mg comprimidos de libertação prolongada	not available	9609800	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Rofenid Long Acting 200 mg, harde capsules met verlengde afgifte	not available	BE140095	SANOFI BELGIUM	BE
Oruvail 150 mg Prolonged-Release Capsules, Hard	not available	PL 04425/0598	AVENTIS PHARMA LTD	UK
PROFENID 100 mg cápsulas	not available	4630299	SANOFI - PRODUTOS	PT

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			FARMACEUTICOS LDA	
Orudis 100 mg solución inyectable	not available	55857	SANOFI-AVENTIS, S.A.	ES
Rofenid Long Acting 200 mg, gélules à libération prolongée	not available	BE140095	SANOFI BELGIUM	BE
Rofenid Ready Mix I.M. 100 mg, solution injectable	not available	BE132063	SANOFI BELGIUM	BE
PROFENID 100 mg supositórios	not available	9424101	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Birofenid 150 mg, comprimés à libération modifiée	not available	BE148066	SANOFI BELGIUM	BE
Rofenid Long Acting 200 mg, gélules à libération prolongée	not available	BE140095	SANOFI BELGIUM	BE
Sprintafen, 25 mg, granulát powlekany	NL/H/3583/001	24139	OMEGA PHARMA LTD	PL
Sprintafen 25 mg omhuld granulaat	not available	RVG 118238	OMEGA PHARMA LTD	NL
Sprintafen 25mg Rakeet	NL/H/3583/001	33753	OMEGA PHARMA LTD	FI