



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2016
EMA/256049/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance(s): nimesulide (systemic formulations)

Procedure No.: PSUSA/00009236/201506



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
Algimesil		029074010	Francia Farmaceutici Industria Farmaco Biologica S.R.L.	Italy
Algimesil		029074022	Francia Farmaceutici Industria Farmaco Biologica S.R.L.	Italy
Algolider		028509026	Siar Pharma S.R.L.	Italy
Alldone		II-14866	Tchaikapharma High Quality Medicines, Inc.	Bulgaria
Aponil		04-0208	Medochemie Ltd.	Latvia
Aponil		17417	Medochemie Ltd.	Cyprus
Aponil		7762/2015/01 & 7762/2015/02	Medochemie Ltd.	Romania
Aponil		LT/1/04/3135/001 & LT/1/04/3135/002 & LT/1/04/3135/003	Medochemie Ltd.	Lithuania
Aulin		6646/2014/05	Angelini Pharma österreich Gmbh	Romania
Aulin		6646/2014/06	Angelini Pharma österreich Gmbh	Romania
Aulin		6647/2014/01 & 6647/2014/02 & 6647/2014/03 & 6647/2014/04	Angelini Pharma österreich Gmbh	Romania
Aulin		6647/2014/05 & 6647/2014/06	Angelini Pharma österreich Gmbh	Romania
Aulin	IT/H/0151/001	025940026 & 025940166 & 025940178 & 025940180 & 025940192 & 025940204	Helsinn Birex Pharmaceuticals Ltd.	Italy
Aulin	IT/H/0151/001	29/0282/97-S	Angelini Pharma česká Republika S.R.O.	Slovakia
Aulin	IT/H/0151/001	29/179/97-C	Angelini Pharma česká Republika S.R.O.	Czech Republic
Aulin	IT/H/0151/001	4113	Angelini Pharma česká Republika S.R.O.	Poland
Aulin	IT/H/0151/001	5809181	Angelini Farmacêutica, Lda	Portugal
Aulin	IT/H/0151/001	5810882	Angelini Farmacêutica, Lda	Portugal
Aulin	IT/H/0151/001	H/01/00240/001 & H/01/00240/002 & H/01/00240/003 & H/01/00240/004 & H/01/00240/005 & H/01/00240/006	Angelini Pharma österreich Gmbh / CSC Pharmaceuticals Handels GmbH	Slovenia
Aulin	IT/H/0151/002	025940053 & 025940115 & 025940127 & 025940139 & 025940141 & 025940154	Helsinn Birex Pharmaceuticals Ltd.	Italy
Aulin	IT/H/0151/002	29/0311/03-S	Angelini Pharma česká Republika S.R.O.	Slovakia
Aulin	IT/H/0151/002	29/180/97-C	Angelini Pharma česká Republika S.R.O.	Czech Republic
Aulin	IT/H/0151/002	4114	Angelini Pharma česká Republika S.R.O.	Poland
Aulin	IT/H/0151/002	H/01/00240/007 & H/01/00240/008 & H/01/00240/009 & H/01/00240/010 &	Angelini Pharma österreich Gmbh / CSC Pharmaceuticals Handels GmbH	Slovenia

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		H/01/00240/011 & H/01/00240/012 & H/01/00240/013 & H/01/00240/014 & H/01/00240/015 & H/01/00240/016 & H/01/00240/017 & H/01/00240/018		
Aulin	IT/H/0151/003	025940065	Helsinn Birex Pharmaceuticals Ltd.	Italy
Aulin 100		6646/2014/01 & 6646/2014/02 & 6646/2014/03 & 6646/2014/04	Angelini Pharma österreich Gmbh	Romania
Аулин		9600168	Angelini Pharma Bulgaria Eood	Bulgaria
Аулин		9700287	Angelini Pharma Bulgaria Eood	Bulgaria
Bioxidol		8371/1-3-1996	Pharmathen International S.A.	Greece
Cliovyl		43073/04-07-2013	Sja Pharm Ltd	Greece
Discorid		8504	Bros Ltd	Greece
Dolostop		39572/29.05.2014	Ioulia And Irene Tseti Pharmaceutical Laboratories S.A.	Greece
Dolostop		44044/10/31.05.2011	Ioulia And Irene Tseti Pharmaceutical Laboratories S.A.	Greece
Dolostop		44053/10/31.05.2011	Ioulia And Irene Tseti Pharmaceutical Laboratories S.A.	Greece
Dolostop		44055/10/31.05.2011	Ioulia And Irene Tseti Pharmaceutical Laboratories S.A.	Greece
Domes		029478017	So.Se.Pharm S.R.L.	Italy
Domes		029478056	So.Se.Pharm S.R.L.	Italy
Efridol		032932016	Aesculapius Farmaceutici S.R.L.	Italy
Efridol		032932030	Aesculapius Farmaceutici S.R.L.	Italy
Erreflog		035364013	Errekappa Euroterapici Spa	Italy
Fansulide		034029013	Sofar S.P.A.	Italy
Fansulide		034029025	Sofar S.P.A.	Italy
Fladalgin		17054/18-7-2011	Proel Epam G Koronis Sa Pharmaceuticals	Greece
Flogostop		57301/7-11-11	D.A.S.T. Biotech Pharm Ltd	Greece
Ingrel		65449/14/16-01-2015	Naturalia S.A.	Greece
Isodol		032337014	Magis Farmaceutici S.P.A.	Italy

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Isodol		032337038	Magis Farmaceutici S.P.A.	Italy
Kartal		28806/19-04-2013	Finixfarm Ltd	Greece
Lalide		18041/30-03-2004	Medochemie Hellas Sa	Greece
Lalide		20207/22-3-2007	Medochemie Hellas Sa	Greece
Ledoren		028519015	S.F. Group Srl	Italy
Ledoren		028519039	S.F. Group Srl	Italy
Lemesilin		53106/12/25-02-2013	Anfarm Hellas Sa	Greece
Mesulid		36240	Boehringer Ingelheim Ellas Ae	Greece
Mesulid		36241	Boehringer Ingelheim Ellas Ae	Greece
Mesulid	IT/H/0150/001	025971021 & 025971173 & 025971185 & 025971197 & 025971209 & 025971211	Helsinn Birex Pharmaceuticals Ltd.	Italy
Mesulid	IT/H/0150/001	29/125/01-C	Angelini Pharma österreich Gmbh	Czech Republic
Mesulid	IT/H/0150/001	97-0248	Helsinn Birex Pharmaceuticals Ltd.	Latvia
Mesulid	IT/H/0150/001/MRP	OGYI-T-6459/01	Angelini Pharma österreich Gmbh	Hungary
Mesulid	IT/H/0150/002	025971058 & 025971110 & 025971122 & 025971134 & 025971146 & 025971159	Helsinn Birex Pharmaceuticals Ltd.	Italy
Mesulid	IT/H/0150/002	29/124/01-C	Angelini Pharma österreich Gmbh	Czech Republic
Mesulid	IT/H/0150/002	OGYI-T-6459/02	Angelini Pharma österreich Gmbh	Hungary
Mesulid	IT/H/0150/003	025971060	Helsinn Birex Pharmaceuticals Ltd.	Italy
Myxina		43052/07	Norma Hellas S.A.	Greece
Nerelid		033078015	New Research Srl	Italy
Nerelid		033078027	New Research Srl	Italy
Nimed		29/415/99-C	Helsinn Birex Pharmaceuticals Ltd.	Czech Republic
Nimed		4567095 & 4567194 & 9692137	Helsinn Birex Pharmaceuticals Ltd.	Portugal
Nimed		4567392 & 4567491 & 9599258	Helsinn Birex Pharmaceuticals Ltd.	Portugal
Nimed	IT/H/0150/001	29/0098/98-S	Helsinn Birex Pharmaceuticals Ltd.	Slovakia
Nimedex		029120019	Italfarmaco S.P.A	Italy
Nimedex		029120021 & 029120033	Italfarmaco S.P.A	Italy

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Nimelide		14436/24-2-2012	Geneparm S.A.	Greece
Nimesil		00-0460	Laboratori Guidotti S.P.A.	Latvia
Nimesil		10403	Laboratori Guidotti S.P.A.	Poland
Nimesil		29/0267/03-S	Laboratori Guidotti S.P.A.	Slovakia
Nimesil		29/118/02-C	Laboratori Guidotti S.P.A.	Czech Republic
Nimesil		LT/1/99/0503/001 & LT/1/99/0503/002 & LT/1/99/0503/003	Laboratori Guidotti S.P.A.	Lithuania
Nimesulene		029007046	Laboratori Guidotti S.P.A.	Italy
Nimesulene		029007059	Laboratori Guidotti S.P.A.	Italy
Nimesulene		029007061	Laboratori Guidotti S.P.A.	Italy
Nimesulene		4613980 & 4614087	Laboratori Guidotti S.P.A.	Portugal
Nimesulida		3625498	Germed Farmacêutica, Lda.	Portugal
Nimesulida Almus		4521696 & 4521795	Almus, Lda	Portugal
Nimesulida Alter		5313192; 5313291	Alter, S.A.	Portugal
Nimesulida Baldacci		5876396	Baldacci - Portugal, S.A.	Portugal
Nimesulida Basi		5791694	Laboratórios Basi – Indústria Farmacêutica, S.A.	Portugal
Nimesulida Basi		5791793	Laboratórios Basi – Indústria Farmacêutica, S.A.	Portugal
Nimesulida Bluepharma		5585286	Bluepharma Genéricos - Comércio De Medicamentos, S.A.	Portugal
Nimesulida Ciclum		5405295 & 5405394 & 5563093	Ciclum Farma Unipessoal, Lda	Portugal
Nimesulida Cinfa Cinfa		5186952 & 5186960 & 5186978	Cinfa Portugal, Lda.	Portugal
Nimesulida Farnoz		3589298 & 4522892	Farnoz - Sociedade Técnico Medicinal, S.A.	Portugal
Nimesulida Generis		4205795 & 4205894 & 5410196	Generis Farmacêutica, S.A.	Portugal
Nimesulida Generis		5255997 & 5256094 & 5410089	Generis Farmacêutica, S.A.	Portugal
Nimesulida Germed		3625191 & 4565792	Germed Farmacêutica, Lda.	Portugal
Nimesulida Germed		4565693	Germed Farmacêutica, Lda.	Portugal
Nimesulida Germed		4565990 & 4566097	Germed Farmacêutica, Lda.	Portugal

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Nimesulida Gp		5292891 & 5292990 & 5452990	Gp – Genéricos Portugueses, Lda.	Portugal
Nimesulida Labesfal		5037593 & 5037692 & 5782396	Labesfal Genéricos, S.A.	Portugal
Nimesulida Labesfal		5037890 & 5037999 & 5782495	Labesfal Genéricos, S.A.	Portugal
Nimesulida Mer		5657184 & 5657283	Mer Medicamentos, Lda.	Portugal
Nimesulida Mylan		4564092 & 4564191	Mylan, Lda	Portugal
Nimesulida Mylan		4564290 & 4564399 & 5012513	Mylan, Lda	Portugal
Nimesulida Neuride		3589595 & 4529194	Tecnimede - Sociedade Técnico-Medicinal, Sa	Portugal
Nimesulida Pentafarma		4522298 & 4522397	Pentafarma - Sociedade Tecnico-Medicinal S.A.	Portugal
Nimesulida Pharmakern		5313499 & 5313598 & 5876495	Pharmakern Portugal – Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Portugal
Nimesulida Ratiopharm		5293196 & 5293295 & 5843891	Ratiopharm-Comercio E Industria De Produtos Farmaceuticos Lda; Ed 5a, Piso 2, Porto Salvo; Portugal	Portugal
Nimesulida Sandoz	04/H/0273/001	5456793 & 5456892 & 5456991	1a Pharma Produtos Farmacêuticos S.A.	Portugal
Nimesulide		033950027	Germed Pharma S.P.A.	Italy
Nimesulide Almus		034200016	Almus S.R.L	Italy
Nimesulide Almus		034200028	Almus S.R.L	Italy
Nimesulide Alter		032326023	Laboratori Alter S.R.L.	Italy
Nimesulide Angenerico		032923017	Angenerico Spa	Italy
Nimesulide Angenerico		032923031	Angenerico Spa	Italy
Nimesulide Big Benedetti		028921029	Benedetti & Co. S.P.A.	Italy
Nimesulide Doc Generici		033578016	Doc Generici S.R.L.	Italy
Nimesulide Doc Generici		033578042	Doc Generici S.R.L.	Italy
Nimesulide Dorom		032983025	Teva Italia S.R.L.	Italy
Nimesulide Eg		033649017	Eg Spa	Italy
Nimesulide Eg		033649029	Eg Spa	Italy
Nimesulide Germed		033950015	Germed Pharma S.P.A.	Italy
Nimesulide Hexal		034245011	Hexal S.P.A	Italy

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Nimesulide Hexal	NOT APPLICABLE	034245 011	Hexal S.P.A	Italy
Nimesulide Medochemie		11-0367	Medochemie Ltd.	Latvia
Nimesulide Mylan Generics		033052010	Mylan S.P.A.	Italy
Nimesulide Mylan Generics		033052034	Mylan S.P.A.	Italy
Nimesulide Pensa		029182019	Pensa Pharma S.P.A.	Italy
Nimesulide Pensa		029182033	Pensa Pharma S.P.A.	Italy
Nimesulide Ranbaxy		033702 & 033702022	Ranbaxy Italia S.P.A.	Italy
Nimesulide Ranbaxy		033702022	Ranbaxy Italia S.P.A.	Italy
Nimesulide Sandoz		032095022	Sandoz S.P.A.	Italy
Nimesulide Sandoz	NOT APPLICABLE	032095010	Sandoz S.P.A.	Italy
Nimesulide Sandoz	NOT APPLICABLE	032095022	Sandoz S.P.A.	Italy
Nimesulide Union Health		035106018	Union Health S.R.L	Italy
Nimesulide Union Health		035106020	Union Health S.R.L	Italy
Nimesulide-Ratiopharm		033673017	Ratiopharm Gmbh	Italy
Nimesulide-Ratiopharm		033673029	Ratiopharm Gmbh	Italy
Nimm		17715	Codal Synto Ltd	Cyprus
Pantames		036384016	S.F. Group Srl	Italy
Remov		028799017	Piam Farmaceutici S.P.A.	Italy
Remov		028799031	Piam Farmaceutici S.P.A.	Italy
Remov		MA037/00501	Piam Farmaceutici S.P.A.	Malta
Remov		MA037/00502	Piam Farmaceutici S.P.A.	Malta
Solving		032930012	Mdm Spa	Italy
Solving		032930036	Mdm Spa	Italy
Specilid	39427/21-10-2009	39427/21-10-2009	Alet Pharmaceuticals Sa	Greece
Sulidamor		028705022	Farmaceutici Damor	Italy
Tranzicalm		42407/21-06-2010	Vocate φαρμακευτική αε	Greece
Ventor		40854/07/6-10-2008	Rafarm Sa.	Greece

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Ventor		40856/07/6-10-2008	Rafarm Sa.	Greece
Volonten		25576	Viofar Ltd	Greece
Xilox		OGYI-T-9791/01 & OGYI-T-9791/02 & OGYI-T-9791/03	Laboratori Guidotti S.P.A.	Hungary
μiv-α-Pon (Minapon)		34618	Minerva Pharmaceutical S.A	Greece
амеолин		20060632	Sopharma Ad	Bulgaria
енетра (Enetra)		20040572	Actavis Ead	Bulgaria
нимед	IT/H/0150/001	20060230	Angelini Pharma Bulgaria Eood	Bulgaria
нимезил		20000819	Laboratori Guidotti S.P.A.	Bulgaria
Minesulin		9971	Pabianickie Zakłady Farmaceutyczne Polfa S.A.	Poland
Minesulin		9972	Pabianickie Zakłady Farmaceutyczne Polfa S.A.	Poland
Nimesil		10403	Laboratori Guidotti S.P.A.	Poland
Nimesulide 100mg tablet		53964/06/15-06-2007	Help S.A.	Greece
Melicat nimesulide			Coup S.A./Abee	Greece
Ritamine			Demo	Greece
Mosuolit			Help	Greece