



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2016
EMA/60776/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: isotretinoin

Procedure no.: PSUSA/00001795/201505



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
A-Cnotren		45045/10/18-04-2012	Pharmathen Hellas S.A.	Greece
A-Cnotren		45047/10/18-04-2012	Pharmathen Hellas S.A.	Greece
A-Cnotren	DK/H/889/01-02/MR	33495/23-05-2007	Pharmathen Hellas S.A.	Greece
Accuran		18066/21-03-2012	Nexus Medicals S.A.	Greece
Accutin		31531 & 31532	Sandoz A/S	Denmark
Acnemin		65413 & 65414	Laboratorios Viñas, S.A.	Spain
Acnenor	DK/H/2242/001 & DK/H/2242/002	51479 & 51480	Actavis Group Ptc Ehf.	Denmark
Acnetrait		NL 26226, NL 26227 & NL 36265	Arrow Generiques	France
Acnetrait		NL 36266	Arrow Generiques	France
Acnogen		38591/10/18-04-2011 & 38594/10/18-04-2011	Genepharm S.A.	Greece
Actaven	DK/H/2242/001 & DK/H/2242/002	21632 & 21633	Actavis Group Ptc Ehf.	Poland
Aisoskin		035258019 & 035258021	Fidia Farmaceutici S.P.A	Italy
Aknenormin	DE/H/1702/001 & DE/H/1702/002	46/0129/05-S & 46/0130/05-S	Almirall Hermal Gmbh	Slovakia
Aknenormin	DE/H/1702/001 & DE/H/1702/002	46/138/05-C & 46/139/05-C	Almirall Hermal Gmbh	Czech Republic
Aknenormin	DE/H/1702/001 & DE/H/1702/002	55003.00.00 & 55003.01.00	Almirall Hermal Gmbh	Germany
Aknenormin	DE/H/1702/001 & DE/H/1702/002	OGYI-T-10170/01 & OGYI-T-10171/01	Almirall Hermal Gmbh	Hungary
Aknenormin	DE/H/1702/002	11426 & 11427	Almirall Hermal Gmbh	Poland
Axotret		11318 & 11319	Axxon Sp. Z O.O.	Poland
Ciscumed 5 mg - Kapseln	AT/H/0164/001	1-27153	Ennogen Healthcare Ltd	Austria

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Ciscutan		1-27652	Pelpharma Handels Gmbh	Austria
Ciscutan		1-29997 & 135651	Pelpharma Handels Gmbh	Austria
Ciscutan	AT/H/0293/001 & AT/H/0293/002	1-24652 & 1-24653	Pelpharma Handels Gmbh	Austria
Contracne		34009 382 601 9 9, 34009 382 602 5 0, 358 116-7, 358 117-3, 358 119-6, 358 120-4, 358 121-0 358 122-7, 367 884-3 & 367 888-9	Laboratoires Bailleul Sa	France
Curacne	FR/H/250/01, FR/H/250/02, FR/H/250/03 & FR/H/250/04	11918, 11919, 11920 & 14709	Pierre Fabre Dermatologie	Poland
Curacne	FR/H/250/01, FR/H/250/02, FR/H/250/03 & FR/H/250/04	358 115 0, 358 123 3, 358 129 1 & 367 603.4	Pierre Fabre Dermatologie	France
Curacne	FR/H/250/01, FR/H/250/02, FR/H/250/03 & FR/H/250/04	52744/19-7-2011, 58331/12-9-2008, 58332/12-9-2008 & 58333/12-9-2008	Pierre Fabre Hellas / Greece	Greece
Curacné	FR/H/0250/002	46/056/06-C	Pierre Fabre Dermatologie	Czech Republic
Curacné	FR/H/0250/003	46/054/06-C	Pierre Fabre Dermatologie	Czech Republic
Curacné	FR/H/0250/004	46/095/08-C	Pierre Fabre Dermatologie	Czech Republic
Curacne	FR/H/250/04	1128/08010002	Pierre Fabre Dermatologie	Luxembourg
Curacne	FR/H/250/04	46/0119/08-S	Pierre Fabre Dermatologie	Slovakia
Curacne Ge	FR/H/250/01, FR/H/250/02 & FR/H/250/03	1128/09020249, 1128/09020250 & 1128/09020251	Pierre Fabre Dermatologie	Luxembourg
Decutan		MA155/00501 & MA155/00502	Actavis Group Hf.	Malta
Decutan	DK/H/0368/001	IS/1/02/035/01	Actavis Hf.	Iceland
Decutan	DK/H/0368/002	IS/1/02/035/02	Actavis Hf.	Iceland
Dercutane		65.333 & 65.334	Industrial Farmaceutica	Spain

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			Cantabria, S.A.	
Dercutane		67.878, 69.742 & 78.326	Industrial Farmaceutica Cantabria, S.A.	Spain
Inerta	DK/H/2242/001 & DK/H/2242/002	OGYI-T-22560/01, OGYI-T-22560/02, OGYI-T-22560/03, OGYI-T-22560/04, OGYI-T-22560/05, OGYI-T-22560/06-10, OGYI-T-22560/07, OGYI-T-22560/08, OGYI-T-22560/09, OGYI-T-22560/10, OGYI-T-22560/11 & OGYI-T-22560/12	Actavis Group Ptc Ehf.	Hungary
Isdiben	UK/H/0504/001 & UK/H/0504/002	66.121 & 66.122	Isdin, S.A.	Spain
Isdiben	UK/H/3577/001, UK/H/3577/002 & UK/H/3577/003	041853019, 041853021, 041853033, 041853045, 041853058, 041853060, 041853072, 041853084 & 041853096	Isdin S.R.L.	Italy
Isdiben	UK/H/3577/001 & UK/H/3577/004	76.045 & 76022	Isdin, S.A.	Spain
Isdiben	UK/H/3577/004	041853108, 041853110 & 041853122	Isdin S.R.L.	Italy
Isoacne	FR/H/250/01, FR/H/250/02, FR/H/250/03 & FR/H/250/04	67464, 67570, 67571 & 69927	Pierre Fabre Iberica / Spain	Spain
Isocural	FR/H/250/01, FR/H/250/02, FR/H/250/03 & FR/H/250/04	BE280402, BE280411, BE280427 & BE334047	Pierre Fabre Benelux	Belgium
Isoderm		18136 & 18137	Sun-Farm Sp. Z.O.O. (Kolbiel)	Poland
Isoderm		427573 8903.00.00 & 48903.01.00	Dermapharm Ag	Germany
Isomacne	DK/H/0368/001 &	33136 & 33137	Actavis Group Ptc Ehf.	Denmark

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	DK/H/0368/002			
Isoriac	FR/H/250/02 & FR/H/250/03	037551013/M & 037551064/M	Pierre Fabre Italia S.P.A.	Italy
Isosupra Lidose		BE 266533 & BE 266542	Laboratoires Smb S.A.	Belgium
Isotret	DK/H/0300/001 & DK/H/0300/002	54100.00.00 & 54100.01.00	Hexal Ag	Germany
Isotretinoin Actavis	DK/H/0297/001 & DK/H/0297/002	17179 & 17180	Actavis Group Ptc Ehf.	Finland
Isotretinoin Actavis	DK/H/0297/001 & DK/H/0297/002	54253.00.00 & 54253.01.00	Actavis Deutschland Gmbh & Co. Kg	Germany
Isotretinoin Actavis	DK/H/0297/001 & DK/H/1747/001	31471 & 37461	Actavis Group Ptc Ehf.	Denmark
Isotretinoin Actavis	DK/H/0297/002	31472	Actavis Group Ptc Ehf.	Denmark
Isotretinoin Actavis	DK/H/1747/001	27968	Actavis Group Ptc Ehf.	Finland
Isotretinoin Actavis	DK/H/2242/001	46/0418/13-S	Actavis Group Ptc Ehf.	Slovakia
Isotretinoin Actavis	DK/H/2242/001 & DK/H/2242/002	48555 & 48556	Actavis Group Ptc Ehf.	Sweden
Isotretinoin Actavis	DK/H/2242/002	46/0419/13-S	Actavis Group Ptc Ehf.	Slovakia
Isotretinoin Alliance Pharmaceuticals		PL 16853/0132 & PL 16853/0133	Alliance Pharmaceuticals Ltd	United Kingdom
Isotretinoin Ennogen Healthcare		PL 40739/0001	Ennogen Healthcare Limited	United Kingdom
Isotretinoin Ennogen Healthcare Limited		PL 40739/0002	Ennogen Healthcare Limited	United Kingdom
Isotretinoin Generics Uk		PL 4569/0723	Generics [uk] Limited	United Kingdom
Isotretinoin Generics	UK/H/3577/001,	PL 04569/1343, PL 04569/1344,	Generics [uk] Limited	United Kingdom

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[uk]	UK/H/3577/002, UK/H/3577/003 & UK/H/3577/004	PL 04569/1345 & PL 04569/1346		
Isotretinoin Generics [uk]	UK/H/3577/002	19732	Generics [uk] Limited	Poland
Isotretinoin Jenson	UK/H/3577/001, UK/H/3577/002 & UK/H/3577/004	19731, 19733 & 19734	Generics [uk] Limited	Poland
Isotretinoin Orifarm	DK/H/1060/001 & DK/H/1060/002	07-5310 & 07-5311	Orifarm Generics A/S	Norway
Isotretinoin Orifarm	DK/H/1060/001 & DK/H/1060/002	34484 & 34485	Orifarm Generics A/S	Denmark
Isotretinoin Orifarm	DK/H/1060/001 & DK/H/1060/002	47763 & 47764	Orifarm Generics A/S	Sweden
Isotretinoin Orifarm	DK/H/1060/002	24197	Orifarm Generics A/S	Finland
Isotretinoin Orion	DK/H/889/01-02/MR	21907	Pharmathen S.A.	Finland
Isotretinoin Orion	DK/H/889/01-02/MR	34932 & 34933	Pharmathen S.A.	Denmark
Isotretinoin Portfarma		IS/1/08/142/01 & IS/1/08/142/02	Portfarma Ehf	Iceland
Isotretinoin Ranbaxy (Uk) Limited		PL 14894/0161 & PL 14894/0162	Ranbaxy (Uk) Limited	United Kingdom
Isotretinoin Ratiopharm	DK-H-0298-001-002	1-24648 & 1-24649	Ratiopharm Arzneimittel Vertriebs-GmbH	Austria
Isotretinoin Ratiopharm	DK-H-0298-001-002	17152	Ratiopharm GmbH	Finland
Isotretinoin Ratiopharm	DK-H-0298-001-002	31473 & 31474	Teva Denmark A/S	Denmark
Isotretinoin	DK-H-0298-001-002	54096.00.00 & 54096.01.00	Ratiopharm GmbH	Germany

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Ratiopharm				
Isotretinoin Ratiopharm	DK-H-0298-001-002	IS/1/14/036/01	Ratiopharm Gmbh	Iceland
Isotretinoin Regiomedica		86943.00.00	Regiomedica Gmbh	Germany
Isotretinoin Sandoz Ltd	NL/H/0593/001 & NL/H/0593/002	PL 04416/1032 & PL 04416/1033	Sandoz Ltd	United Kingdom
Isotretinoin-Teva		OGYI-T-20238/01, OGYI-T-20238/02, OGYI-T-20238/03, OGYI-T-20238/04, OGYI-T-20238/05, OGYI-T-20238/06, OGYI-T-20238/07, OGYI-T-20238/08, OGYI-T-20238/09 & OGYI-T-20238/10	Teva Gyógyszergyár Zrt	Hungary
Isotretinoina Difa	DK/H/1749/001	039964010, 039964022, 039964034, 039964046, 039964059, 039964061, 039964073, 039964085, 039964097 & 039964109	Difa Cooper S.P.A.	Italy
Isotretinoina Difa Cooper	DK/H/0298/001, DK/H/0298/001-002 & DK/H/0298/002	036083018, 036083020, 036083032, 036083044, 036083057/M, 036083069/M, 036083071/M, 036083083/M, 036083095/M & 036083107/M	Difa Cooper S.P.A.	Italy
Isotretinoina Pierre Fabre	FR/H/250/01, FR/H/250/02 & FR/H/250/03	5731989, 5732482 & 5732987	Pfdc / Portugal	Portugal
Isotretinoina Stiefel	UK/H/0327/001	034912016	Stiefel Laboratories (Ireland) Ltd	Italy
Isotretinoína Actavis	DK/H/0297/001-002	4057881	Actavis A/S Sucursal	Portugal
Isotretinoína Generis		4882296, 4882395, 5113923, 5113931,	Generis Farmacêutica, S.A.	Portugal

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		5161492, 5161591, 5503297 & 5503396		
Isotretinoína Mer		5677893, 5677992, 5678099, 5678198, 5678297 & 5678396	Mer Medicamentos, Lda.	Portugal
Isotretinoína Orotrex		4882494, 4882593, 5174693, 5174792 & 5174891	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
Isotretinoïne 10 Pch	NL-H-902-001	RVG 27575	Pharmachemie B.V.	Netherlands
Isotretinoïne 20 Pch	NL-H-902-002	RVG 27576	Pharmachemie B.V.	Netherlands
Isotretinoïne Aurobindo	DK/H/0297/001 & DK/H/0297/002	RVG 27577 & RVG 27578	Aurobindo Pharma B.V.	Netherlands
Isotretinoïne stada	BE/H/0193/001 & BE/H/0193/002	0019/05060039 & 0019/05060040	Eurogenerics Sa	Luxembourg
Isotretinoïne Eurogenerics	BE/H/0193/001, BE/H/0193/002	BE266296 & BE270173	Eurogenerics Sa	Belgium
Isotretinoïne Mylan	UK/H/0504/002 & UK/H/0504/003	RVG 27573 & RVG 27574	Mylan B.V.	Netherlands
Isotretinoïne Sandoz	NL/H/0593/001 & NL/H/0593/002	RVG 26547 & RVG 26548	Sandoz B.V.	Netherlands
Isotretinoïne Sandoz	NL/H/0593/002	BE291137	Sandoz N.V.	Belgium
Isotrex		028997017	Stiefel Laboratories (Ireland) Ltd	Italy
Isotrex		1-21786	Glaxosmithkline Pharma Gmbh.	Austria
Isotrex		15297	Stiefel Laboratories (Ireland) Ltd	Denmark
Isotrex		2219681	Laboratorios Farmaceuticos	Portugal

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			Stiefel (Portugal) Ltda	
Isotrex		29915.00.00	Glaxosmithkline Gmbh & Co. Kg	Germany
Isotrex		60.235	Stiefel Farma, S.A.	Spain
Isotrex		7614	Stiefel Laboratories (Ireland) Ltd	Poland
Isotrex		MA 300/00901	Glaxosmithkline Uk Limited	Malta
Isotrex		PA 1077/122/1	Glaxosmithkline (Ireland) Limited	Ireland
Isotrex		PL 19494/0063	Glaxosmithkline Uk Limited	United Kingdom
Isotrex	UK/H/0327/001 & UK/H/0327/002	46570.00.00 & 46570.01.00	Glaxosmithkline Gmbh & Co. Kg	Germany
Isotrex	UK/H/0327/001 & UK/H/0327/002	PL 19494/0069 & PL 19494/0070	Glaxosmithkline Uk Limited	United Kingdom
Isotroin		20693, 20695 & S00714/30-6-2010	Iasis Pharma	Cyprus
Isotroin		76447/10-11-11, 76449/10-11-11 & 78135/10-11-11	Iasis Pharma	Greece
Isotrétinoïne Eurogenerics	BE/H/0193/001	BE266296	Eurogenerics Sa	Belgium
Izotek	DK/H/0889/001 & DK/H/0889/002	12349 & 12350	Pharmaswiss česká Republika S.R.O.	Poland
Izotziaja		11145	Ziaja Ltd Zakład Produkcji Leków Sp Z O.O.	Poland
Mayesta		69.571 & 69.572	Bama-Geve, S.L.U.	Spain
Pharmiso	DK/H/0300/001 & DK/H/0300/002	31477 & 31478	Hexal Ag	Denmark
Procuta		34009 357 836 6 0, 34009 357 837 2 1,	Laboratoires Expanscience	France

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		34009 357 838 9 9, 34009 357 839 5 0, 34009 357 840 3 2, 34009 358 104 9 6, 34009 358 105 5 7, 34009 358 106 1 8, 34009 358 107 8 6, 34009 358 108 4 7, 34009 358 109 0 8, 34009 358 110 9 7, 34009 358 111 5 8, 34009 358 112 1 9 & 34009 367 880 8 4		
Procuta		34009 357 842 6 1	Laboratoires Expanscience	France
Reducar		39324/14-6-2013 & 41918/14-6-2013	Gap A.E.	Greece
Roaccutan	UK/H/0666/001	OGYI-T-1278/01	Roche (Magyarország) Kft	Hungary
Roaccutan	UK/H/0666/002	OGYI-T-1278/02	Roche (Magyarország) Kft	Hungary
Roaccutan	UK/H/666/001	9220	Roche Oy	Finland
Roaccutan	UK/H/666/002	9221	Roche Oy	Finland
Roaccutane		20030084	Roche Bulgaria Eood	Bulgaria
Roaccutane		7449/2006/01	Roche Romania Srl	Romania
Roaccutane		NL 17429-3400933471705	Societe D'etudes Et De Recherches Pharmaceutiques (Serp)	France
Roaccutane		UPI-530-09/10-02/414	Roche D.O.O.	Croatia
Roaccutane	NL/H/666/001	052294	Roche Eesti Oü	Estonia
Roaccutane	NL/H/666/002	404002	Roche Eesti Oü	Estonia
Roaccutane	UK-H-666	BE130611	N.V. Roche S.A.	Luxembourg
Roaccutane	UK-H-666	BE130627	N.V. Roche S.A.	Luxembourg
Roaccutane	UK/H/0666/001/	LT/1/05/0406/001	Uab 'roche Lietuva'	Lithuania
Roaccutane	UK/H/0666/001/	LT/1/05/0406/002	Uab 'roche Lietuva'	Lithuania
Roaccutane	UK/H/0666/001/	LT/1/05/0406/003	Uab 'roche Lietuva'	Lithuania

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Roaccutane	UK/H/0666/001/	LT/1/05/0406/004	Uab 'roche Lietuva'	Lithuania
Roaccutane	UK/H/0666/002/	LT/1/05/0406/005	Uab 'roche Lietuva'	Lithuania
Roaccutane	UK/H/0666/002/	LT/1/05/0406/006	Uab 'roche Lietuva'	Lithuania
Roaccutane	UK/H/0666/002/	LT/1/05/0406/007	Uab 'roche Lietuva'	Lithuania
Roaccutane	UK/H/0666/002/	LT/1/05/0406/008	Uab 'roche Lietuva'	Lithuania
Roaccutane	UK/H/666	05-0517	Roche Latvija Sia	Latvia
Roaccutane	UK/H/666/001 & UK/H/666/002	PA 50/53/4 & PA 50/53/5	Roche Products Ltd	Ireland
Roaccutane	UK/H/666/001	PL 00031/0617	Roche Products Ltd	United Kingdom
Roaccutane	UK/H/666/002	PL 00031/0160	Roche Products Ltd	United Kingdom
Roaccutane	UK/H/666/01 & UK/H/666/02	46/0360/05-S	Roche Slovensko S.R.O.	Slovakia
Roaccutane	UK/H/666/01	BE130611	N.V. Roche S.A.	Belgium
Roaccutane	UK/H/666/01/R/02	363-I-214/12	Roche Farmaceutvska Družba D.O.O.	Slovenia
Roaccutane	UK/H/666/02	BE130627	N.V. Roche S.A.	Belgium
Rocne		87229/7-12-2009 & 87230/7-12-2009	Pharmathen S.A.	Greece
Rotren		20320 & 20321	Sapiens Pharmaceuticals Ltd	Cyprus
Sotret		6765/2014/01 & 6766/2014/01	SC Terapia S.A.	Romania
Sotret		OGYI-T- 8989/01, OGYI-T- 8989/02, OGYI-T- 8989/03, OGYI-T- 8989/04, OGYI-T- 8989/08, OGYI-T-8989/05, OGYI-T-8989/06 & OGYI-T-8989/07	SC Terapia S.A.	Hungary
Stiefotrex		65279/12/02-04-13	Glaxosmithkline Aebe	Greece
Tretin		66319/14/07-01-2015	Target Pharma Single Member Private Ltd	Greece
Tretin		66320/14/07-01-2015 & 85176/14/07-	Target Pharma Single	Greece

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		01-2015	Member Private Ltd	
Tretinex		12053 & 12054	Medana Pharma Spolka Akcyjna	Poland
Tretiosan	DK/H/1748/001	37462	Hexal Ag	Denmark
Rotaxin		21122 & 21123	Hadjiconstantinou Bros Ltd	Cyprus
Roaccutane	UK/H/0666/001	RVG 10305	Roche Nederland B.V.	Netherlands
Roaccutane	UK/H/0666/002	RVG 10306	Roche Nederland B.V.	Netherlands
Isotrex 500µg/g gel		7614	Stiefel Laboratories (Ireland) Ltd	Ireland
Isotretinoin Orifarm	DK/H/1060/001-002/MR	71368.00.00, 71369.00.00	Orifarm Generics A/S	Germany