



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2023
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Oral retinoids: (Acitretin, Alitretinoin, Isotretinoin)

Procedure no.: EMEA/H/N/PSR/J/0040

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Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
CISCUTAN 10 MG – KAPSELN	National procedure	1-24652	PELPHARMA HANDELS GMBH	Austria
CISCUTAN 20 MG – KAPSELN	National procedure	1-24653	PELPHARMA HANDELS GMBH	Austria
CISCUTAN 30 MG – KAPSELN	National procedure	135651	PELPHARMA HANDELS GMBH	Austria
CISCUTAN 40 MG – KAPSELN	National procedure	1-27652	PELPHARMA HANDELS GMBH	Austria
CISCUTAN 5 MG – KAPSELN	National procedure	1-29997	PELPHARMA HANDELS GMBH	Austria
KERACUTAN 10 MG KAPSELN	National procedure	1-31432	PELPHARMA HANDELS GMBH	Austria
KERACUTAN 25 MG KAPSELN	National procedure	1-31433	PELPHARMA HANDELS GMBH	Austria
Neotigason 10 mg Kapseln	National procedure	1-18708	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Austria
Neotigason 25 mg Kapseln	National procedure	1-18709	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Austria
TOCTINO 10 MG WEICKAPSELN	DK/H/1377/001	1-28037	GLAXOSMITHKLINE PHARMA GMBH.	Austria

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
TOCTINO 30 MG WEICHKAPSELN	DK/H/1377/002	1-28038	GLAXOSMITHKLINE PHARMA GMBH.	Austria
ISOCURAL 10 mg, soft capsule	FR/H/250/02	BE280411	Pierre Fabre Benelux SA Boulevard Paepsem 8 1070 Bruxelles Belgium	Belgium
ISOCURAL 20 mg, soft capsule	FR/H/250/03	BE280427	Pierre Fabre Benelux SA Boulevard Paepsem 8 1070 Bruxelles Belgium	Belgium
ISOCURAL 40 mg, soft capsule	FR/H/250/04	BE 334047	Pierre Fabre Benelux SA Boulevard Paepsem 8 1070 Bruxelles Belgium	Belgium
ISOCURAL 5 mg, soft capsule	FR/H/250/01	BE280402	Pierre Fabre Benelux SA Boulevard Paepsem 8 1070 Bruxelles Belgium	Belgium
ISOSUPRA LIDOSE 16 MG HARTKAPSELN	National procedure	BE266542	LABORATOIRES SMB S.A	Belgium
ISOSUPRA LIDOSE 16 MG, CAPSULES, HARD	National procedure	BE266542	LABORATOIRES SMB S.A	Belgium
ISOSUPRA LIDOSE 16 MG, GÉLULES	National procedure	BE266542	LABORATOIRES SMB S.A	Belgium
ISOSUPRA LIDOSE 8 MG HARTKAPSELN	National procedure	BE266533	LABORATOIRES SMB S.A	Belgium
ISOSUPRA LIDOSE 8 MG, CAPSULES, HARD	National procedure	BE266533	LABORATOIRES SMB S.A	Belgium

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
ISOSUPRA LIDOSE 8 MG, GÉLULES	National procedure	BE266533	LABORATOIRES SMB S.A	Belgium
Isotretinoïne EG 10 mg capsules, zacht	BE/H/0193/001	BE266296	Eurogenerics N.V./S.A.	Belgium
Isotretinoïne EG 20 mg capsules, zacht	BE/H/0193/002	BE270173	Eurogenerics N.V./S.A.	Belgium
ISOTRETINOÏNE SANDOZ 20 MG ZACHTE CAPSULES	NL/H/0593	BE291137	SANDOZ N.V.	Belgium
Neotigason 10 mg harde capsules	National procedure	BE144706	Aurobindo Pharma B.V.	Belgium
Neotigason 25 mg harde capsules	National procedure	BE144602	Aurobindo Pharma B.V.	Belgium
Roaccutane 10 mg capsules molles	EE/H/0271/001	BE130611	N.V. Roche S.A.	Belgium
Roaccutane 20 mg capsules molles	EE/H/0271/002	BE130627	N.V. Roche S.A.	Belgium
*Neotigason 10 mg capsules, hard	National procedure	20010476	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Bulgaria
Роакутан 20 мг капсули, меки	National procedure	20030084	Roche Bulgaria EOOD	Bulgaria

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Neotigason 10 mg tvrde kapsule	National procedure	HR-H-047281874	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Croatia
Neotigason 25 mg tvrde kapsule	National procedure	HR-H-770001325	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Croatia
Roaccutane 10 mg meke kapsule	National procedure	HR-H-462694255	Roche d.o.o.	Croatia
ISOTROIN 10mg καψάκια μαλακά	National procedure	1st MA: 20695/3-06-2010 (Latest approved: 204-31/11T(G12), 14-2-2011)	IASIS PHARMACEUTICALS HELLAS ABEE	Cyprus
ISOTROIN 20mg καψάκια μαλακά	National procedure	1st MA: 20693/3-06-2010 (Latest approved: 204-31/11T(G12), 14-2-2011)	IASIS PHARMACEUTICALS HELLAS ABEE	Cyprus
ISOTROIN 40mg καψάκια μαλακά	Special Marketing Authorisation	S00714/30-6-2010	IASIS PHARMACEUTICALS HELLAS ABEE	Cyprus
Neotigason	National procedure	S00096	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Cyprus
Neotigason	National procedure	S00097	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Cyprus
Rotaxin	National procedure	21123	Hadjiconstantinou Bros Ltd	Cyprus

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Rotaxin	National procedure	21122	Hadjiconstantinou Bros Ltd	Cyprus
Aknenormin (isotretinoin) Soft capsule 10 mg	DE/H/1702/001/MR	46/138/05-C	ALMIRALL HERMAL GmbH	Czech Republic
Aknenormin (isotretinoin) Soft capsule 20 mg	DE/H/1702/002/MR	46/139/05-C	ALMIRALL HERMAL GmbH	Czech Republic
CURACNÉ 10 mg, soft capsule	FR/H/250/02	46/056/06-C	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Czech Republic
CURACNÉ 20 mg, soft capsule	FR/H/250/03	46/054/06-C	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Czech Republic
CURACNÉ 40 mg, soft capsule	FR/H/250/04	46/095/08-C	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Czech Republic
Neotigason 10 mg	National procedure	46/145/95-A/C	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Czech Republic
Neotigason 25 mg	National procedure	46/145/95-B/C	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Czech Republic
ACCUTIN	National procedure	31531-2000	SANDOZ A/S	Denmark

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ACCUTIN	National procedure	31532-2000	SANDOZ A/S	Denmark
Acitretin Orifarm, 10 mg capsules hard	DK/H/2552/001	56275	Orifarm Generics A/S	Denmark
Acitretin Orifarm, 10 mg capsules hard	DK/H/2552/002	56280	Orifarm Generics A/S	Denmark
Acnenor	DK-H-2242-001-002-DC	51479	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark
Acnenor	DK-H-2242-001-002-DC	51480	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark
Isomacne	DK-H-0368-001-002	33137	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark
Isomacne	DK-H-0368-001-002	33136	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark
Isotretinoin Actavis	DK-H-0297-001-002	31472	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark
Isotretinoin Actavis	DK-H-1747-001-MRP	37461	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoin Actavis	DK-H-0297-001-002	31471	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark
Isotretinoin Orifarm 10 mg capsules, soft	DK/H/1060/001	34484	Orifarm Generics A/S	Denmark
Isotretinoin Orifarm 20 mg capsules, soft	DK/H/1060/002	34485	Orifarm Generics A/S	Denmark
Isotretinoin Orion	DK/H/889/01-02/MR	34932	Pharmathen S.A.	Denmark
Isotretinoin Orion	DK/H/889/01-02/MR	34933	Pharmathen S.A.	Denmark
ISOTRETINOIN-RATIOPHARM , BLØDE KAPSLER	DK-H-0298-001-002	31473	Teva B.V Swensweg 5 2031GA Haarlem Netherlands	Denmark
ISOTRETINOIN-RATIOPHARM , BLØDE KAPSLER	DK-H-0298-001-002	31474	Teva B.V Swensweg 5 2031GA Haarlem Netherlands	Denmark
Neotigason	National procedure	13124	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark
Neotigason	National procedure	13125	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Denmark

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
PHARMISO	DK/H/0300	31477	HEXAL AG	Denmark
PHARMISO	DK/H/0300	31478	HEXAL AG	Denmark
TOCTINO	DK/H/1377/001	42008	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Denmark
TOCTINO , BLØDE KAPSLER	DK/H/1377/002	42009	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Denmark
Neotigason	National procedure	83694	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Estonia
Roaccutane 10 mg, pehmekapslid	EE/H/0271/001	52294	Roche Eesti OÜ	Estonia
Roaccutane 20 mg, pehmekapslid	EE/H/0271/002	404002	Roche Eesti OÜ	Estonia
Acitretin Orifarm, 10 mg capsules hard	DK/H/2552/001	33560	Orifarm Generics A/S	Finland
Acitretin Orifarm, 10 mg capsules hard	DK/H/2552/002	33561	Orifarm Generics A/S	Finland
Isotretinoin Actavis 10mg kapseli, pehmeä	DK-H-0297-001-002	17179	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Finland

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoin Actavis 20 mg kapseli, pehmeä	DK-H-0297-001-002	17180	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Finland
Isotretinoin Actavis 40 mg kapseli, pehmeä	DK-H-1747-001-MRP	27968	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Finland
Isotretinoin Orifarm 20 mg capsules, soft	DK/H/1060/002	24197	Orifarm Generics A/S	Finland
Isotretinoin Orion	DK/H/889/01-02/MR	21907	Pharmathen S.A.	Finland
Isotretinoin-ratiopharm 20 mg kapseli, pehmeä	FI-H-0993-002-MR	17152	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Finland
Neotigason 10 mg kapseli, kova	National procedure	10116	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Finland
Neotigason 25 mg kapseli, kova	National procedure	10117	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Finland
TOCTINO 10 MG KAPSELIT, PEHMEÄ	DK/H/1377/001	24078	GLAXOSMITHKLINE OY, FI, ESPOO	Finland
TOCTINO 10 MG MJUKA KAPSLAR	DK/H/1377/001	24078	GLAXOSMITHKLINE OY, FI, ESPOO	Finland
TOCTINO 30 MG KAPSELIT, PEHMEÄ	DK/H/1377/002	24079	GLAXOSMITHKLINE OY, FI, ESPOO	Finland

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TOCTINO 30 MG MJUKA KAPSLAR	DK/H/1377/002	24079	GLAXOSMITHKLINE OY, FI, ESPOO	Finland
ACNETRAIT 10 MG, CAPSULE MOLLE	National procedure	26226	Arrow Génériques	France
ACNETRAIT 20 MG, CAPSULE MOLLE	National procedure	26227	Arrow Génériques	France
ACNETRAIT 40 MG, CAPSULE MOLLE	National procedure	36266	Arrow Génériques	France
ACNETRAIT 5 MG, CAPSULE MOLLE	National procedure	36265	Arrow Génériques	France
Contracne 10 mg, capsule molle	National procedure	34009 358 120 4 9 (NL 26247)	Laboratoires Bailleul S.A.	France
Contracne 10 mg, capsule molle	National procedure	34009 358 121 0 0 (NL 26247)	Laboratoires Bailleul S.A.	France
Contracne 10 mg, capsule molle	National procedure	34009 358 122 7 8 (NL 26247)	Laboratoires Bailleul S.A.	France
Contracne 20 mg, capsule molle	National procedure	34009 358 116 7 7 (NL 26248)	Laboratoires Bailleul S.A.	France
Contracne 20 mg, capsule molle	National procedure	34009 358 117 3 8 (NL 26248)	Laboratoires Bailleul S.A.	France

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Contracne 20 mg, capsule molle	National procedure	34009 358 119 6 7 (NL 26248)	Laboratoires Bailleul S.A.	France
Contracne 40 mg, capsule molle	National procedure	34009 367 884 3 5 (NL 30576)	Laboratoires Bailleul S.A.	France
Contracne 40 mg, capsule molle	National procedure	34009 367 888 9 3 (NL 30576)	Laboratoires Bailleul S.A.	France
Contracne 5 mg, capsule molle	National procedure	34009 382 601 9 9 (NL 32798)	Laboratoires Bailleul S.A.	France
Contracne 5 mg, capsule molle	National procedure	34009 382 602 5 0 (NL 32798)	Laboratoires Bailleul S.A.	France
CURACNÉ 10 mg, soft capsule	FR/H/250/02	34009 358 129 1 9 34009 358 131 6 9 34009 358 132 2 0 34009 358 133 9 8 34009 358 134 5 9	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	France
CURACNÉ 20 mg, soft capsule	FR/H/250/03	34009 358 135 1 0 34009 358 136 8 8 34009 358 115 0 9 34009 358 157 5 0 34009 358 158 1 1	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	France
CURACNÉ 40 mg, soft capsule	FR/H/250/04	34009 367 603 4 9	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	France
CURACNÉ 5 mg, soft capsule	FR/H/250/01	34009 358 123 3 9 34009 358 125 6 8 34009 358 126 2 9 34009 358 127 9 7 34009 358 128 5 8	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	France

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
PROCUTA 10 mg, capsule molle	National procedure	CIS 6 525 037 5 CIP 34009 357 838 9 9 : 30 soft capsules in thermoform blister	LABORATOIRES EXPANSCIENCE	France
PROCUTA 20 mg, capsule molle	National procedure	CIS 6 795 224 9 CIP 34009 357 836 6 0 : 30 soft capsules in thermoform blister	LABORATOIRES EXPANSCIENCE	France
PROCUTA 40 mg, capsule molle	National procedure	CIS 6 768 229 8 CIP 34009 367 880 8 4 : 30 soft capsules in thermoform blister	LABORATOIRES EXPANSCIENCE	France
PROCUTA 5 mg, capsule molle	National procedure	CIS 6 931 644 9 CIP 34009 357 840 3 2 : 30 soft capsules in thermoform blister	LABORATOIRES EXPANSCIENCE	France
SORIATANE 10 MG, GÉLULE	National procedure	15451	Arrow Génériques	France
SORIATANE 25 MG, GÉLULE	National procedure	15452	Arrow Génériques	France
TOCTINO 10 MG, CAPSULE MOLLE	DK/H/1377/001	NL34847	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	France
TOCTINO 30 MG, CAPSULE MOLLE	DK/H/1377/002	NL34848	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	France
Acicutan 10 mg Hartkapseln	DE/H/5797/001/DC	81208.00.00	Dermapharm AG	Germany
Acicutan 25 mg Hartkapseln	DE/H/5797/002/DC	81209.00.00	Dermapharm AG	Germany

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Aknenormin (isotretinoin) Soft capsule 10 mg	DE/H/1702/001/MR	55003.00.00	ALMIRALL HERMAL GmbH	Germany
Aknenormin (isotretinoin) Soft capsule 20 mg	DE/H/1702/002/MR	55003.01.00	ALMIRALL HERMAL GmbH	Germany
Isoderm 10 mg	National procedure	48903.00.00	Dermapharm AG	Germany
Isoderm 20 mg	National procedure	48903.01.00	Dermapharm AG	Germany
IsoGalen 10 mg Weichkapseln	DK/H/1060/001-002/MR	71368.00.00	GALENpharma GmbH	Germany
IsoGalen 20 mg Weichkapseln	DK/H/1060/001-002/MR	71369.00.00	GALENpharma GmbH	Germany
ISOTRET-HEXAL 10 MG KAPSELN	DK/H/0300	54100.00.00	HEXAL AG	Germany
ISOTRET-HEXAL 20 MG KAPSELN	DK/H/0300	54100.01.00	HEXAL AG	Germany
ISOTRETINOIN BASICS 10 mg Weichkapseln	NL/H/3739/001	97279.00.00	BASICS GMBH, DE, LEVERKUSEN	Germany
ISOTRETINOIN BASICS 20 mg Weichkapseln	NL/H/3739/002	97280.00.00	BASICS GMBH, DE, LEVERKUSEN	Germany

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Isotretinoin PUREN 10 mg Weichkapseln	PT/H/1878/001	54253.00.00	PUREN Pharma GmbH & CO. KG	Germany
Isotretinoin PUREN 20 mg Weichkapseln	PT/H/1878/002	54253.01.00	PUREN Pharma GmbH & CO. KG	Germany
Isotretinoin-ratiopharm 10 mg Weichkapseln	DK-H-0298-001-002	54096.00.00	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Germany
Isotretinoin-ratiopharm 20 mg Weichkapseln	DK-H-0298-001-002	54096.01.00	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Germany
Neotigason 10	National procedure	22414.00.00	PUREN Pharma GmbH & CO. KG	Germany
Neotigason 25	National procedure	22414.01.00	PUREN Pharma GmbH & CO. KG	Germany
TOCTINO 10 MG WEICHKAPSELN	DK/H/1377/001	71216.00.00	GLAXOSMITHKLINE GMBH & CO. KG	Germany
TOCTINO 30 MG WEICHKAPSELN	DK/H/1377/002	71255.00.00	GLAXOSMITHKLINE GMBH & CO. KG	Germany
CEHADO 10 mg καψάκια μαλακά	DK/H/1377/001	2884101	GLAXOSMITHLINE α.ε.β.ε	Greece
CEHADO 30 mg καψάκια μαλακά	DK/H/1377/002	2884102	GLAXOSMITHLINE α.ε.β.ε	Greece

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Neotigason	National procedure	60863/12/11-11-2013	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Greece
Neotigason	National procedure	85248/11-11-2013	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Greece
Tretin	National procedure	66320/14/07-01-2015	TARGET PHARMA SINGLE MEMBER PRIVATE LTD	Greece
Tretin	National procedure	85176/14/07-01-2015	TARGET PHARMA SINGLE MEMBER PRIVATE LTD	Greece
A-cnotren	DK/H/889/01-02/MR	84432/11/20-09-2013 (45/16-01-2012)	Pharmathen Hellas S.A. imminent change of MAH to: Pharmathen Investments Group Limited	Greece (EL)
A-cnotren	National procedure	22836/9-7-2002 (45047/10/18-04-2012)	Pharmathen Hellas S.A. imminent change of MAH to: Pharmathen Investments Group Limited	Greece (EL)
ISOTROIN 10mg καψάκια μαλακά	National procedure	1 st MA: 9045/26-2-2003 (Latest approved: 76447/10-11-11)	IASIS PHARMACEUTICALS HELLAS ABEE	Greece (EL)
ISOTROIN 20mg καψάκια μαλακά	National procedure	1 st MA: 3585/10-7-2002 (Latest approved: 76449/10-11-11)	IASIS PHARMACEUTICALS HELLAS ABEE	Greece (EL)
ISOTROIN 40mg καψάκια μαλακά	National procedure	1 st MA: 12210/06/29-11-07 (Latest approved: 78135/10-11-11)	IASIS PHARMACEUTICALS HELLAS ABEE	Greece (EL)
REDUCAR	National procedure	10mg: 2624301 20mg: 2624302 (EMA portal - 41918/14-	GAP S.A.	Greece (EL)

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		6-2013, 39324/14-6-2013)		
ROCNE	National procedure	22268/01-04-2014 (87229/7-12-2009)	Pharmathen S.A.	Greece (EL)
ROCNE	National procedure	22268/01-04-2014 (87230/7-12-2009)	Pharmathen S.A.	Greece (EL)
Aknenormin (isotretinoin) Soft capsule 10 mg	DE/H/1702/001/MR	OGYI-T-10170/01	ALMIRALL HERMAL GmbH	Hungary
Aknenormin (isotretinoin) Soft capsule 20 mg	DE/H/1702/002/MR	OGYI-T-10171/01	ALMIRALL HERMAL GmbH	Hungary
Inerta 10 mg lágy kapszula	DK-H-2242-001-002-DC	OGYI-T-22560/01-05, 11	Actavis Group PTC ehf Reykjavíkurveg 76-78 220 Hafnarfjörður Iceland	Hungary
Inerta 20 mg lágy kapszula	DK-H-2242-001-002-DC	OGYI-T-22560/06-10, 12	Actavis Group PTC ehf Reykjavíkurveg 76-78 220 Hafnarfjörður Iceland	Hungary
Isotretinoin-Teva 10 mg lágy kapszula	National procedure	OGYI-T-20238/01	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Isotretinoin-Teva 10 mg lágy kapszula	National procedure	OGYI-T-20238/02	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Isotretinoin-Teva 10 mg lágy kapszula	National procedure	OGYI-T-20238/03	Teva Gyógyszergyár Zrt Pallagi ut 13	Hungary

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			4042 Debrecen Hungary	
Isotretinoin-Teva 10 mg lágy kapszula	National procedure	OGYI-T-20238/04	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Isotretinoin-Teva 10 mg lágy kapszula	National procedure	OGYI-T-20238/05	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Isotretinoin-Teva 20 mg lágy kapszula	National procedure	OGYI-T-20238/06	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Isotretinoin-Teva 20 mg lágy kapszula	National procedure	OGYI-T-20238/07	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Isotretinoin-Teva 20 mg lágy kapszula	National procedure	OGYI-T-20238/08	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Isotretinoin-Teva 20 mg lágy kapszula	National procedure	OGYI-T-20238/09	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Isotretinoin-Teva 20 mg lágy kapszula	National procedure	OGYI-T-20238/10	Teva Gyógyszergyár Zrt Pallagi ut 13 4042 Debrecen Hungary	Hungary
Neotigason 10 mg kemény kapszula	National procedure	OGYI-T-4469/01	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Hungary

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Neotigason 25 mg kemény kapszula	National procedure	OGYI-T-4469/02	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Hungary
*Sotret Neo 10 mg lágy kapszula	NL/H/3739/001	OGYI-T-23222/01	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Hungary
*Sotret Neo 20 mg lágy kapszula	NL/H/3739/002	OGYI-T-23222/02	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Hungary
Roaccutan 10 mg lágy kapszula	EE/H/0271/001	OGYI-T-1278/01	Roche (Magyarország) Kft	Hungary
Roaccutan 20 mg lágy kapszula	EE/H/0271/002	OGYI-T-1278/02	Roche (Magyarország) Kft	Hungary
Decutan	DK-H-0368-001-002	IS/1/02/035/02	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Iceland
Decutan	DK-H-0368-001-002	IS/1/02/035/01	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Iceland
Isotretinoin ratiopharm 20 mg mjúkt hylki	IS-H-0290-001-MR	IS/1/14/036/01	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Iceland
Neotigason	National procedure	870227 (IS)	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Iceland
Neotigason	National procedure	870226 (IS)	Actavis Group PTC ehf Reykjavíkurvegi 76-78	Iceland

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
			220 Hafnarfjordur Iceland	
TOCTINO 10mg mjúk hylki	DK/H/1377/001	IS/1/09/077/01	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Iceland
TOCTINO 30mg mjúk hylki	DK/H/1377/002	IS/1/09/077/02	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Iceland
Neotigason 10 mg capsules	National procedure	PA 1380/50/1	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Ireland
Neotigason 25 mg capsules	National procedure	PA 1380/50/2	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Ireland
Roaccutane 10 mg Soft Capsules	EE/H/0271/001	PA2307/007/001	Roche Products (Ireland) Ltd	Ireland
Roaccutane 20 mg Soft Capsules	EE/H/0271/002	PA2307/007/002	Roche Products (Ireland) Ltd	Ireland
AISOSKIN	National procedure	035258019	Fidia Farmaceutici S.p.A.	Italy
AISOSKIN	National procedure	035258021	Fidia Farmaceutici S.p.A.	Italy
Isdiben 10 mg capsule molli (100 caps)	UK/H/3577/001-004/DC	041853060	Isdin S.r.l.	Italy

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isdiben 10 mg capsule molli (30 caps)	UK/H/3577/001-004/DC	041853045	Isdin S.r.l.	Italy
Isdiben 10 mg capsule molli (50 caps)	UK/H/3577/001-004/DC	041853058	Isdin S.r.l.	Italy
Isdiben 20 mg capsule molli (100 caps)	UK/H/3577/001-004/DC	041853096	Isdin S.r.l.	Italy
Isdiben 20 mg capsule molli (30 caps)	UK/H/3577/001-004/DC	041853072	Isdin S.r.l.	Italy
Isdiben 20 mg capsule molli (50 caps)	UK/H/3577/001-004/DC	041853084	Isdin S.r.l.	Italy
Isdiben 40 mg capsule molli (100 caps)	UK/H/3577/001-004/DC	041853122	Isdin S.r.l.	Italy
Isdiben 40 mg capsule molli (30 caps)	UK/H/3577/001-004/DC	041853108	Isdin S.r.l.	Italy
Isdiben 40 mg capsule molli (50 caps)	UK/H/3577/001-004/DC	041853110	Isdin S.r.l.	Italy
Isdiben 5 mg capsule molli (100 caps)	UK/H/3577/001-004/DC	041853033	Isdin S.r.l.	Italy
Isdiben 5 mg capsule molli (30 caps)	UK/H/3577/001-004/DC	041853019	Isdin S.r.l.	Italy

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isdiben 5 mg capsule molli (50 caps)	UK/H/3577/001-004/DC	041853021	Isdin S.r.l.	Italy
ISORIAC 10 mg, soft capsule	FR/H/250/02	037551013 037551025 037551037 037551049 037551052	Pierre Fabre Italia SpA Via G. Washington, 70 20146 Milano Italy	Italy
ISORIAC 20 mg, soft capsule	FR/H/250/03	037551064 037551076 037551088 037551090 037551102	Pierre Fabre Italia SpA Via G. Washington, 70 20146 Milano Italy	Italy
Isotretinoina Difa	DK/H/1749/001	37463, 40 mg No reg. 39964/034-085-010-061- 022-073-046-097-059- 109	Difa Cooper spa	Italy
Isotretinoina Difa Cooper	DK/H/0298/001, DK/H/0298/002	314/73-74 10 mg No reg. 036083/020-018-032- 044-057 20 mg No reg. 036083/071-095-069- 083-095	Difa Cooper spa	Italy
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046012	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046063	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046036	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoïna SUN 10 mg capsule molli	NL/H/3739/001	045046024	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoïna SUN 10 mg capsule molli	NL/H/3739/001	045046048	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoïna SUN 10 mg capsule molli	NL/H/3739/001	045046051	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoïna SUN 20 mg capsule molli	NL/H/3739/002	045046075	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoïna SUN 20 mg capsule molli	NL/H/3739/002	045046087	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoïna SUN 20 mg capsule molli	NL/H/3739/002	045046099	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoïna SUN 20 mg capsule molli	NL/H/3739/002	045046113	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoïna SUN 20 mg capsule molli	NL/H/3739/002	045046101	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
Isotretinoïna SUN 20 mg capsule molli	NL/H/3739/002	045046125	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Italy
NEOTIGASON 25 mg capsule rigide	National procedure	027480021	Aurobindo Pharma (Italia) S.r.l.	Italy

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
NEOTIGASON 10 mg capsule rigide,	National procedure	027480019	Aurobindo Pharma (Italia) S.r.l.	Italy
TOCTINO 10 MG CAPSULE MOLLI	DK/H/1377/001	38849016	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Italy
TOCTINO 10 MG CAPSULE MOLLI	DK/H/1377/001	38849028	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Italy
TOCTINO 30 MG CAPSULE MOLLI	DK/H/1377/002	38849030	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Italy
TOCTINO 30 MG CAPSULE MOLLI	DK/H/1377/002	38849042	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Italy
Zorias	NL/H/1961/001, NL/H/1961/002	107/057-058 10 mg No reg. 41619/014-026-053 25 mg No reg. 41619/065-040-038	Difa Cooper spa	Italy
Neotigason 10 mg cietās kapsulas	National procedure	96-0595	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Latvia
Roaccutane 10 mg mīkstās kapsulas	EE/H/0271/001	05-0517	Roche Latvija SIA	Latvia
Roaccutane 20 mg mīkstās kapsulas	EE/H/0271/002	05-0518	Roche Latvija SIA	Latvia
Neotigason 10 mg kietosios kapsulės	National procedure	LT/1/94/0419/001	Actavis Group PTC ehf Reykjavíkurvegi 76-78	Lithuania

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
			220 Hafnarfjordur Iceland	
Roaccutane 10 mg minkštos kapsulės	EE/H/0271/001	LT/1/05/0406/001 – N20 LT/1/05/0406/002 – N30 LT/1/05/0406/003 – N50 LT/1/05/0406/004 – N100	UAB Roche Lietuva	Lithuania
Roaccutane 20 mg minkštos kapsulės	EE/H/0271/002	LT/1/05/0406/005 – N20 LT/1/05/0406/006 – N30 LT/1/05/0406/007 – N50 LT/1/05/0406/008 – N100	UAB Roche Lietuva	Lithuania
CURACNÉ 40 mg, soft capsule	FR/H/250/04	472984	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Luxembourg
CURACNÉ Gé 10 mg, soft capsule	FR/H/250/02	0427913 0427927 0427931 0427944 0427958	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Luxembourg
CURACNÉ Gé 20 mg, soft capsule	FR/H/250/03	0427961 0427975 0427989 0427992 0428003	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Luxembourg
CURACNÉ Gé 5 mg, soft capsule	FR/H/250/01	0427846 0427863 0427877 0427881 0427894	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Luxembourg

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoïne EG 10 mg capsules molles	BE/H/0193/001	0019/05060039	Eurogenerics N.V./S.A.	Luxembourg
Isotretinoïne EG 20mg capsules molles	BE/H/0193/002	0019/05060040	Eurogenerics N.V./S.A.	Luxembourg
Neotigason 10 mg gélules	National procedure	2003107909	Aurobindo Pharma B.V.	Luxembourg
Neotigason 25 mg gélules	National procedure	2003107910	Aurobindo Pharma B.V.	Luxembourg
Roaccutane 10 mg capsules molles	EE/H/0271/001	2010010651	N.V. Roche S.A.	Luxembourg
Roaccutane 20 mg capsules molles	EE/H/0271/002	2010040736	N.V. Roche S.A.	Luxembourg
Acitretin Capsules 25mg	National procedure	AA085/00601	Genus Pharmaceuticals Limited	Malta
Contrace 10 mg, soft capsule	National procedure	AA1106/00401	Laboratoires Bailleul S.A.	Malta
Contrace 20 mg, soft capsule	National procedure	AA1106/00402	Laboratoires Bailleul S.A.	Malta
Decutan	National procedure	628/17401	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Malta

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Decutan	National procedure	628/17402	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Malta
Neotigason	National procedure	MA628/04102	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Malta
Neotigason	National procedure	MA628/04101	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Malta
Acitretine CF 10mg Capsules	NL/H/1959/001	RVG 107065	Centrafarm B.V.	Netherlands
Acitretine CF 25mg Capsules	NL/H/1959/002	RVG 107066	Centrafarm B.V.	Netherlands
Isotretinoïne Aurobindo 10 mg, capsules	PT/H/1878/001-002/MR	RVG 27577	Aurobindo Pharma B.V.	Netherlands
Isotretinoïne Aurobindo 20 mg, capsules	PT/H/1878/001-002/MR	RVG 27578	Aurobindo Pharma B.V.	Netherlands
Isotretinoïne Capsules [10 mg] [Blister (All)]	UK/H/0504	RVG 27573	Mylan BV	Netherlands
Isotretinoïne Capsules [20 mg] [Blister (All)]	UK/H/0504	RVG 27574	Mylan BV	Netherlands
Isotretinoïne SUN 10 mg, zachte capsules	NL/H/3739/001	RVG 119052	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFFDORP	Netherlands

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoïne SUN 20 mg, zachte capsules	NL/H/3739/002	RVG 119053	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Netherlands
Neotigason 10 mg, capsules	National procedure	RVG 13103	Aurobindo Pharma B.V.	Netherlands
Neotigason 25 mg, capsules	National procedure	RVG 13104	Aurobindo Pharma B.V.	Netherlands
TOCTINO 10 MG, CAPSULES, ZACHT	DK/H/1377/001	RVG 100957	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Netherlands
TOCTINO 30 MG, CAPSULES, ZACHT	DK/H/1377/002	RVG 100962	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Netherlands
Acitretin Orifarm, 10 mg capsules hard	DK/H/2552/001	15-10784	Orifarm Generics A/S	Norway
Acitretin Orifarm, 10 mg capsules hard	DK/H/2552/002	15-10785	Orifarm Generics A/S	Norway
Isotretinoin Orifarm 10 mg capsules, soft	DK/H/1060/001	07-5310	Orifarm Generics A/S	Norway
Isotretinoin Orifarm 20 mg capsules, soft	DK/H/1060/002	07-5311	Orifarm Generics A/S	Norway
Neotigason	National procedure	7760	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Norway

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Neotigason	National procedure	7759	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Norway
TOCTINO 10 MG KAPSLER, MYKE	DK/H/1377/001	1758887	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Norway
TOCTINO 30 MG KAPSLER, MYKE	DK/H/1377/002	1759253	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Norway
Acitren 10mg kapsulki	DE/H/5797/001/DC	18728	Sun-Farm So. z.o.o.	Poland
Acitren 25mg kapsulki	DE/H/5797/002/DC	18729	Sun-Farm So. z.o.o.	Poland
Actaven	DK-H-2242-001-DC	21632	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Poland
Actaven	DK-H-2242-002-DC	21633	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Poland
Aknenormin (isotretinoin) Soft capsule 10 mg	DE/H/1702/001/MR	11427	ALMIRALL HERMAL GmbH	Poland
Aknenormin (isotretinoin) Soft capsule 20 mg	DE/H/1702/002/MR	11426	ALMIRALL HERMAL GmbH	Poland
AXOTRET	National procedure	11318, 11319	AXXON Sp. z o.o.	Poland

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
CURACNE 10 mg, soft capsule	FR/H/250/02	11919	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Poland
CURACNE 20 mg, soft capsule	FR/H/250/03	11918	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Poland
CURACNE 40 mg, soft capsule	FR/H/250/04	14709	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Poland
CURACNE 5 mg, soft capsule	FR/H/250/01	11920	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Poland
Isoderm 10 mg kapsulki, miekkie	National procedure	18136	Sun-Farm So. z.o.o.	Poland
Isoderm 20 mg kapsulki, miekkie	National procedure	18137	Sun-Farm So. z.o.o.	Poland
Izotek	DK/H/0889/001/MR	12349	PharmaSwiss Ceska republika s.r.o.	Poland
Izotek	DK/H/0889/002/MR	12350	PharmaSwiss Ceska republika s.r.o.	Poland
Neotigason	National procedure	R/6969	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Poland

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Neotigason	National procedure	R/6970	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Poland
Sotret 10 mg, kapsułki miękkie	NL/H/3739/001	24226	RANBAXY POLAND SP. ZO.O, PL, WARSAW	Poland
Sotret 20 mg, kapsułki miękkie	NL/H/3739/002	24227	RANBAXY POLAND SP. ZO.O, PL, WARSAW	Poland
TOCTINO kapsulki micrkkie 30 mg	DK/H/1377/002	17606	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Poland
TOCTINO kapsulki micrkkie 10 mg	DK/H/1377/001	17605	STIEFEL LABORATORIES LEGACY (IRELAND) LTD	Poland
Isotretinoína Aurovitas	PT/H/1878/01-02	4057782 4057584 4057683 4057881 4057980 4058087 4058285 4058384 4058186 4058483	Generis Farmacêutica, S.A.	Portugal
Isotretinoína Generis	National procedure	5503297 4882296 5161591 5113923 5503396 4882395 5161492 5113931	Generis Farmacêutica, S.A.	Portugal

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
ISOTRETINOÍNA OROTREX 10 MG CÁPSULAS MOLES	National procedure	5174693	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
ISOTRETINOÍNA OROTREX 10 MG CÁPSULAS MOLES	National procedure	5174792	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
ISOTRETINOÍNA OROTREX 10 MG CÁPSULAS MOLES	National procedure	4882494	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
ISOTRETINOÍNA OROTREX 20 MG CÁPSULAS MOLES	National procedure	4882593	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
ISOTRETINOÍNA OROTREX 20 MG CÁPSULAS MOLES	National procedure	5174891	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
ISOTRETINOÍNA OROTREX 5 MG CÁPSULAS MOLES	National procedure	5750518	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
ISOTRETINOÍNA OROTREX 5 MG CÁPSULAS MOLES	National procedure	5750526	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Portugal
Neotigason	National procedure	8756411 8756403 8756437 8756429	Generis Farmacêutica, S.A.	Portugal
Neotigason 10 mg capsule	National procedure	9699/2017/01	Actavis Group PTC ehf Reykjavíkurvegi 76-78 220 Hafnarfjörður Iceland	Romania
Roaccutane 10 mg capsule moi	National procedure	7661/2015/01	Roche Romania SRL	Romania

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/02	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/01	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/06	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/05	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/04	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/03	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/01	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/02	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/03	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/04	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/05	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/06	TERAPIA S.A., RO, CLUJ-NAPOCA	Romania
Aknenormin (isotretinoin) Soft capsule 10 mg	DE/H/1702/001/MR	46/0130/05-S	ALMIRALL HERMAL GmbH	Slovakia
Aknenormin (isotretinoin) Soft capsule 20 mg	DE/H/1702/002/MR	46/0129/05-S	ALMIRALL HERMAL GmbH	Slovakia
CURACNÉ 40 mg, soft capsule	FR/H/250/04	46/0119/08-S	PIERRE FABRE DERMATOLOGIE 45 place Abel Gance 92100 BOULOGNE France	Slovakia
Isotretinoin Actavis 10 mg	DK-H-2242-001-002-DC	46/0418/13-S	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Slovakia
Isotretinoin Actavis 20 mg	DK-H-2242-001-002-DC	46/0419/13-S	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Slovakia
Neotigason 10 mg	National procedure	46/0661/95-S	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Slovakia
Neotigason 25 mg	National procedure	46/0263/15-S	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Slovakia

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
TOCTINO 10 MG MÄKKÉ KAPSULY	DK/H/1377/001	46/0139/10-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	Slovakia
TOCTINO 30 MG MÄKKÉ KAPSULY	DK/H/1377/002	46/0140/10-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	Slovakia
NEOTIGASON ® 25 mg trde kapsule	National procedure	H/96/01103/002	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Slovenia
NEOTIGASON ®10 mg trde kapsule	National procedure	H/96/01103/001	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Slovenia
TOCTINO 10 MG MEHKE KAPSULE	DK/H/1377/001	H/10/01534/001	GLAXOSMITHKLINE D.O.O.	Slovenia
TOCTINO 30 MG MEHKE KAPSULE	DK/H/1377/002	H/10/01534/002	GLAXOSMITHKLINE D.O.O.	Slovenia
Roaccutane 10 mg mehke kapsule	EE/H/0271/001	H/96/01368/001	Roche farmacevtska družba d.o.o.	Slovenia
Roaccutane 20 mg mehke kapsule	EE/H/0271/002	H/96/01368/005	Roche farmacevtska družba d.o.o.	Slovenia
Acitretina IFC	NL/H/1961/001, NL/H/1961/002	10 mg No reg. 74727 25 mg No reg. 74726	Industrial Farmacéutica Cantabria, S.A.	Spain
Dercutane	National procedure	5 mg No reg. 69742 10 mg No reg. 65333 20 mg No reg. 65334	Industrial Farmacéutica Cantabria, S.A.	Spain

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
		30 mg No reg. 78326 40 mg No reg. 67878		
Flexresan 10 mg cápsulas blandas/ Flexresan 20 mg cápsulas blandas	National procedure	66.160/ 66.159	Especialidades Farmacéuticas Centrum, S.A.	Spain
Isdiben 10 mg cápsulas blandas	UK/H/0504/001-003/MR	66121	ISDIN SA	Spain
Isdiben 20 mg cápsulas blandas	UK/H/0504/001-003/MR	66122	ISDIN SA	Spain
Isdiben 40 mg cápsulas blandas	UK/H/3577/001-004/DC	76045	ISDIN SA	Spain
ISOACNE 10 mg, soft capsule	FR/H/250/02	67.570	Pierre Fabre Iberica SA Ramon Trias Fargas, 7-11 Edificio Marina Village 08005 Barcelona - Spain	Spain
ISOACNE 20 mg, soft capsule	FR/H/250/03	67.571	Pierre Fabre Iberica SA Ramon Trias Fargas, 7-11 Edificio Marina Village 08005 Barcelona - Spain	Spain
ISOACNE 40 mg, soft capsule	FR/H/250/04	69.927	Pierre Fabre Iberica SA Ramon Trias Fargas, 7-11 Edificio Marina Village 08005 Barcelona - Spain	Spain
ISOACNE 5 mg, soft capsule	FR/H/250/01	67.464	Pierre Fabre Iberica SA Ramon Trias Fargas, 7-11 Edificio Marina Village 08005 Barcelona - Spain	Spain
Isotretinoína SUN 10 mg cápsulas blandas	NL/H/3739/001	82566	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Spain

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoína SUN 20 mg cápsulas blandas	NL/H/3739/002	82567	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	Spain
MAYESTA 10 MG CÁPSULAS BLANDAS	National procedure	69571	ALFASIGMA ESPAÑA, S.L.	Spain
MAYESTA 20 MG CÁPSULAS BLANDAS	National procedure	69572	ALFASIGMA ESPAÑA, S.L.	Spain
Neotigason 10 mg cápsulas duras	National procedure	60303	Aurovitas Spain, S.A.U.	Spain
Neotigason 25 mg cápsulas duras	National procedure	60302	Aurovitas Spain, S.A.U.	Spain
TOCTINO 10 MG CÁPSULAS BLANDAS	DK/H/1377/001	70.843	STIEFEL FARMA, S.A.	Spain
TOCTINO 30 MG CÁPSULAS BLANDAS	DK/H/1377/002	70.844	STIEFEL FARMA, S.A.	Spain
Acitretin Orifarm, 10 mg capsules hard	DK/H/2552/001	53202	Orifarm Generics A/S	Sweden
Acitretin Orifarm, 10 mg capsules hard	DK/H/2552/002	53203	Orifarm Generics A/S	Sweden
Isotretinoin Actavis	DK-H-2242-001-002-DC	48556	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Sweden

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoin Actavis	DK-H-2242-001-002-DC	48555	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Sweden
Isotretinoin Orifarm 10 mg capsules, soft	DK/H/1060/001	57967	Orifarm Generics A/S	Sweden
Isotretinoin Orifarm 20 mg capsules, soft	DK/H/1060/002	57968	Orifarm Generics A/S	Sweden
Neotigason	National procedure	12743	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Sweden
Neotigason	National procedure	12742	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	Sweden
Acitretin 10mg Capsules	NL/H/1959/001	PL 06831/0251	Genus Pharmaceuticals Limited	United Kingdom
Acitretin 25mg Capsules	NL/H/1959/002	PL 06831/0252	Genus Pharmaceuticals Limited	United Kingdom
Isotretinoin 10 mg Capsules	National procedure	PL 14894/0161	RANBAXY (UK) LIMITED, GB, HAYES	United Kingdom
Isotretinoin 10 mg Soft Capsules	UK/H/3577	PL 04569/1344	Generics (UK) Ltd T/A Mylan	United Kingdom
Isotretinoin 10 mg Soft Capsules	UK/H/0504	PL 04569/0725	Generics (UK) Ltd T/A Mylan	United Kingdom

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoin 10 mg soft capsules	NL/H/3739/001	PL 31750/0099	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	United Kingdom
Isotretinoin 20 mg Capsules	National procedure	PL 14894/0162	RANBAXY (UK) LIMITED, GB, HAYES	United Kingdom
Isotretinoin 20 mg Soft Capsules	UK/H/3577	PL 04569/1345	Generics (UK) Ltd T/A Mylan	United Kingdom
Isotretinoin 20 mg Soft Capsules	UK/H/0504	PL 04569/0724	Generics (UK) Ltd T/A Mylan	United Kingdom
Isotretinoin 20 mg soft capsules	NL/H/3739/002	PL 31750/0100	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V., NL, HOOFDDORP	United Kingdom
Isotretinoin 20mg Capsules, Rizuderm 20mg Capsules	National procedure	PL 16853/0133	Alliance Pharmaceuticals Limited	United Kingdom
Isotretinoin 20mg soft capsules	National procedure	PL40739/0001	Ennogen Healthcare Limited	United Kingdom
Isotretinoin 40 mg Soft Capsules	UK/H/3577	PL 04569/1346	Generics (UK) Ltd T/A Mylan	United Kingdom
Isotretinoin 5 mg Soft Capsules	UK/H/3577	PL 04569/1343	Generics (UK) Ltd T/A Mylan	United Kingdom
Isotretinoin 5 mg Soft Capsules	UK/H/0504	PL 04569/0726	Generics (UK) Ltd T/A Mylan	United Kingdom

Product Name (in authorisation country)	MRP/DCP Authorisation number	Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Isotretinoin 5mg Capsules	UK/H/7020/001/DC (old: AT/H/0164/001)	PL 40739/0002	Ennogen Healthcare Limited	United Kingdom
Isotretinoin 5mg Capsules, Rizuderm 5mg Capsules	National procedure	PL 16853/0132	Alliance Pharmaceuticals Limited	United Kingdom
Neotigason 10mg Capsules	National procedure	30306-0096, 30306-0098	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	United Kingdom
Neotigason 25mg Capsules	National procedure	30306/0097	Actavis Group PTC ehf Reykjavikurvegi 76-78 220 Hafnarfjordur Iceland	United Kingdom
Roaccutane 10 mg soft capsules	EE/H/0271/001	PL 00031/0617	Roche Products Ltd	United Kingdom
Roaccutane 20 mg soft capsules	EE/H/0271/002	PL 00031/0160	Roche Products Ltd	United Kingdom
TOCTINO ® 10 MG CAPSULES, SOFT	DK/H/1377/002	PL 19494/0253	GLAXOSMITHKLINE UK LIMITED	United Kingdom
TOCTINO 30 MG CAPSULES, SOFT	DK/H/1377/001	PL 19494/0252	GLAXOSMITHKLINE UK LIMITED	United Kingdom