



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2017
EMA/787886/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: isotretinoin (oral formulations)

Procedure no.: PSUSA/00010488/201705



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
REDUCAR 10mg μαλακό καψάκιο	not available	41918/14-6-2013	GAP S.A.	GR
REDUCAR 20mg μαλακό καψάκιο	not available	39324/14-6-2013	GAP S.A.	GR
Isotretinoin 20 mg soft capsules	NL/H/3739/002	PL 31750/0100	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	UK
Isotretinoin 10 mg soft capsules	NL/H/3739/001	PL 31750/0099	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	UK
Izotek 10 mg, kapsułki, miękkie	DK/H/0889/001	12350	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
Izotek 20 mg, kapsułki, miękkie	DK/H/0889/002	12349	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
Acnemin 10 mg cápsulas blandas	not available	65413	LABORATORIOS VIÑAS, S.A.	ES
Acnemin 20 mg cápsulas blandas	not available	65414	LABORATORIOS VIÑAS, S.A.	ES
Isotretinoin Actavis 5 mg mjúk hylki	not available	IS/1/16/035/01	ACTAVIS GROUP PTC EHF.	IS
Rotaxin 10mg soft gelatin capsules	not available	21122	HADJICONSTANTINOUS BROS	CY
Rotaxin 20mg soft gelatin capsules	not available	21123	HADJICONSTANTINOUS BROS	CY
ISOTROIN® 10mg καψάκια μαλακά	not available	76447/10-11-11	IASIS PHARMA	GR
ISOTROIN® 20mg καψάκια μαλακά	not available	76449/10-11-11	IASIS PHARMA	GR
ISOTROIN® 40mg καψάκια μαλακά	not available	78135/10-11-11	IASIS PHARMA	GR

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
ISOTROIN® 10mg καψάκια μαλακά	not available	20695	IASIS PHARMA	CY
ISOTROIN® 20mg καψάκια μαλακά	not available	20693	IASIS PHARMA	CY
ISOTROIN® 40mg καψάκια μαλακά	not available	S00714	IASIS PHARMA	CY
Isotretinoin "Actavis", bløde kapsler	DK/H/0297/002	31472	ACTAVIS GROUP PTC EHF.	DK
Isotretinoin "Actavis", bløde kapsler	DK/H/0297/001	31471	ACTAVIS GROUP PTC EHF.	DK
ISOTRETINOIN ACTAVIS 10 MG, KAPSELI, PEHMEÄ	DK/H/0297/001	17179	ACTAVIS GROUP PTC EHF.	FI
ISOTRETINOIN ACTAVIS 20 MG, KAPSELI, PEHMEÄ	DK/H/0297/002	17180	ACTAVIS GROUP PTC EHF.	FI
CONTRACNE 5 mg, capsule molle	not available	34009 382 601 9 9	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 5 mg, capsule molle	not available	34009 382 602 5 0	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 10 mg, capsule molle	not available	358 120-4	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 10 mg, capsule molle	not available	358 121-0	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 10 mg, capsule molle	not available	358 122-7	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 20 mg, capsule molle	not available	358 116-7	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 20 mg, capsule molle	not available	358 117-3	LABORATOIRES BAILLEUL SA	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
CONTRACNE 20 mg, capsule molle	not available	358 119-6	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 40 mg, capsule molle	not available	367 884-3	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 40 mg, capsule molle	not available	367 888-9	LABORATOIRES BAILLEUL SA	FR
ISOTRETINOIN "ORION", BLØDE KAPSLER	DK/H/0889/001	34932	PHARMATHEN S.A.	DK
ISOTRETINOIN "ORION", BLØDE KAPSLER	DK/H/0889/002	34933	PHARMATHEN S.A.	DK
Isotretinoin Orion 20 mg kapseli, pehmeä	DK/H/0889/002	21907	PHARMATHEN S.A.	FI
Isotretinoïne 20 PCH, capsules 20 mg	NL/H/902/002	RVG 27576	PHARMACHEMIE B.V	NL
PROCUTA 5 mg, capsule molle	not available	34009 358 110 9 7	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 5 mg, capsule molle	not available	34009 357 840 3 2	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 5 mg, capsule molle	not available	34009 358 111 5 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 5 mg, capsule molle	not available	34009 358 112 1 9	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 5 mg, capsule molle	not available	34009 357 842 6 1	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 358 107 8 6	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 357 838 9 9	LABORATOIRES EXPANSCIENCE	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
PROCUTA 10 mg, capsule molle	not available	34009 358 108 4 7	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 358 109 0 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 357 839 5 0	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 104 9 6	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 357 836 6 0	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 105 5 7	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 106 1 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 357 837 2 1	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 40 mg, capsule molle	not available	34009 367 880 8 4	LABORATOIRES EXPANSCIENCE	FR
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964010	DIFA COOPER S.P.A.	IT
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964022	DIFA COOPER S.P.A.	IT
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964034	DIFA COOPER S.P.A.	IT
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964046	DIFA COOPER S.P.A.	IT
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964059	DIFA COOPER S.P.A.	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
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964061	DIFA COOPER S.P.A.	IT
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964073	DIFA COOPER S.P.A.	IT
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964085	DIFA COOPER S.P.A.	IT
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964097	DIFA COOPER S.P.A.	IT
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964109	DIFA COOPER S.P.A.	IT
Isotretinoin Actavis 40 mg mjúk hylki	not available	IS/1/16/035/02	ACTAVIS GROUP PTC EHF.	IS
Ciscutan 10 mg – Kapseln	AT/H/0293/001	1-24652	PELPHARMA HANDELS GMBH	AT
Ciscutan 20 mg – Kapseln	AT/H/0293/002	1-24653	PELPHARMA HANDELS GMBH	AT
Isdiben 10 mg capsule molli	UK/H/3577/002	041853045	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	UK/H/3577/002	041853058	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	UK/H/3577/002	041853060	ISDIN S.R.L.	IT
Isotretinoin 10 mg Soft Capsules	UK/H/3577/002	PL 04569/1344	GENERICS [UK] LIMITED	UK
Isotretinoin 20 mg Soft Capsules	UK/H/3577/003	PL 04569/1345	GENERICS [UK] LIMITED	UK
Isotretinoin 40 mg Soft Capsules	UK/H/3577/004	PL 04569/1346	GENERICS [UK] LIMITED	UK

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
Isotretinoin 5 mg Soft Capsules	UK/H/3577/001	PL 04569/1343	GENERICS [UK] LIMITED	UK
Isdiben 40 mg cápsulas blandas	UK/H/3577/004	76.045	ISDIN, S.A.	ES
Isdiben 5 mg capsule molli	UK/H/3577/001	041853019	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	UK/H/3577/001	041853021	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	UK/H/3577/001	041853033	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	UK/H/3577/003	041853072	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	UK/H/3577/003	041853084	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	UK/H/3577/003	041853096	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	UK/H/3577/004	041853108	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	UK/H/3577/004	041853110	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	UK/H/3577/004	041853122	ISDIN S.R.L.	IT
ACNETRAIT 5 mg, capsule molle	not available	NL 36265	ARROW GENERIQUES	FR
ACNETRAIT 10 mg, capsule molle	not available	NL 26226	ARROW GENERIQUES	FR
ACNETRAIT 20 mg, capsule molle	not available	NL 26227	ARROW GENERIQUES	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
ACNETRAIT 40 mg, capsule molle	not available	NL 36266	ARROW GENERIQUES	FR
Isotretinoïne EG 20 mg capsules molles	BE/H/0193/002	0019/05060040	EUROGENERICS SA	LU
Isotretinoïne EG 20 mg zachte capsules	BE/H/0193/002	BE270173	EUROGENERICS N.V./S.A.	BE
Isotretinoïne EG 20 mg Weichkapseln	BE/H/0193/002	BE270173	EUROGENERICS N.V./S.A.	BE
Isotretinoïne EG 20 mg capsules molles	BE/H/0193/002	BE270173	EUROGENERICS N.V./S.A.	BE
Isotretinoin 10mg Capsules	not available	PL 14894/0161	RANBAXY UK LTD	UK
Isotretinoin 20mg Capsules	not available	PL 14894/0162	RANBAXY UK LTD	UK
Tretoskin, 10 mg, kapsułki miękkie	not available	12054	VITAMA S.A.	PL
Tretoskin, 10 mg, kapsułki miękkie	not available	12054	VITAMA S.A.	PL
Tretoskin, 20 mg, kapsułki miękkie	not available	12053	VITAMA S.A.	PL
Tretoskin, 20 mg, kapsułki miękkie	not available	12053	VITAMA S.A.	PL
Tretoskin, 20 mg, kapsułki miękkie	not available	12053	VITAMA S.A.	PL
Isotretinoïne EG 10 mg capsules molles	BE/H/0193/001	0019/05060039	EUROGENERICS SA	LU
Isotretinoïne EG 10 mg zachte capsules	BE/H/0193/001	BE266296	EUROGENERICS N.V./S.A.	BE

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
Isotretinoïne EG 10 mg Weichkapseln	BE/H/0193/001	BE266296	EUROGENERICS N.V./S.A.	BE
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	BE266296	EUROGENERICS N.V./S.A.	BE
Roaccutane 10 mg capsule moi	not available	7661/2015/01	ROCHE ROMANIA SRL	RO
Роакутан 20 mg капсули, меки	not available	20030084	ROCHE BULGARIA EOOD	BG
Roaccutane 10 mg meke kapsule	not available	HR-H-462694255	ROCHE D.O.O.	HR
Isotretinoin 5 mg capsules	AT/H/0164/001	PL 40739/0002	ENNOGEN HEALTHCARE LIMITED	UK
Isotretinoin 20mg soft capsules	not available	PL 40739/0001	ENNOGEN HEALTHCARE LIMITED	UK
Reticutan 20mg soft capsules	not available	PL 40739/0001	ENNOGEN HEALTHCARE LIMITED	UK
Ciscumed 5 mg – Kapseln	AT/H/0164/001	1-27153	ENNOGEN HEALTHCARE LIMITED	AT
Isotretinoína Orotrex 10 mg cápsulas moles	not available	5174693	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Isotretinoína Orotrex 10 mg cápsulas moles	not available	4882494	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Isotretinoína Orotrex 10 mg cápsulas moles	not available	5174792	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT

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
Isotretinoína Orotrex 20 mg cápsulas moles	not available	4882593	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Isotretinoína Orotrex 20 mg cápsulas moles	not available	5174891	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
ROCNE	not available	87229/7-12-2009	PHARMATHEN S.A.	GR
ROCNE	not available	87230/7-12-2009	PHARMATHEN S.A.	GR
Aknenormin 10 mg Weichkapseln	DE/H/1702/001	55003.00.00	ALMIRALL HERMAL GMBH	DE
Aknenormin 10 mg měkké tobolky	DE/H/1702/001/MR	46/138/05-C	ALMIRALL HERMAL GMBH	CZ
Aknenormin 10 mg lágy kapszula	DE/H/1702/001	OGYI-T-10170/01	ALMIRALL HERMAL GMBH	HU
Aknenormin, 10 mg, kapsulki miękkie	DE/H/1702/001	11427	ALMIRALL HERMAL GMBH	PL
Aknenormin 10 Mäkké kapsuly	DE/H/1702/001	46/0130/05-S	ALMIRALL HERMAL GMBH	SK
Aknenormin 20 mg Weichkapseln	DE/H/1702/002	55003.01.00	ALMIRALL HERMAL GMBH	DE
Aknenormin 20 mg měkké tobolky	DE/H/1702/002/MR	46/139/05-C	ALMIRALL HERMAL GMBH	CZ
Aknenormin 20 mg lágy kapszula	DE/H/1702/002	OGYI-T-10171/01	ALMIRALL HERMAL GMBH	HU
Aknenormin 20 Mäkké kapsuly	DE/H/1702/002/MR	46/0129/05-S	ALMIRALL HERMAL GMBH	SK

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
Aknenormin, 20 mg, kapsułki miękkie	DE/H/1702/002	11426	ALMIRALL HERMAL GMBH	PL
ACTAVEN, 10 MG, KAPSULKI, MIEKKIE	DK/H/2242/001	21632	ACTAVIS GROUP PTC EHF.	PL
ACTAVEN, 20 MG, KAPSULKI, MIEKKIE	DK/H/2242/002	21633	ACTAVIS GROUP PTC EHF.	PL
Inerta 10 mg lágy kapszula	DK/H/2242/001	OGYI-T-22560/02	ACTAVIS GROUP PTC EHF.	HU
Inerta 10 mg lágy kapszula	DK/H/2242/001	OGYI-T-22560/03	ACTAVIS GROUP PTC EHF.	HU
Inerta 10 mg lágy kapszula	DK/H/2242/001	OGYI-T-22560/04	ACTAVIS GROUP PTC EHF.	HU
Inerta 10 mg lágy kapszula	DK/H/2242/001	OGYI-T-22560/05	ACTAVIS GROUP PTC EHF.	HU
Inerta 10 mg lágy kapszula	DK/H/2242/001	OGYI-T-22560/11	ACTAVIS GROUP PTC EHF.	HU
Inerta 20 mg lágy kapszula	DK/H/2242/002	OGYI-T-22560/07	ACTAVIS GROUP PTC EHF.	HU
Inerta 20 mg lágy kapszula	DK/H/2242/002	OGYI-T-22560/08	ACTAVIS GROUP PTC EHF.	HU
Inerta 20 mg lágy kapszula	DK/H/2242/002	OGYI-T-22560/09	ACTAVIS GROUP PTC EHF.	HU
Inerta 20 mg lágy kapszula	DK/H/2242/002	OGYI-T-22560/10	ACTAVIS GROUP PTC EHF.	HU
Inerta 20 mg lágy kapszula	DK/H/2242/002	OGYI-T-22560/12	ACTAVIS GROUP PTC EHF.	HU
ACNENOR, BLØDE KAPSLER	DK/H/2242/001	51479	ACTAVIS GROUP PTC EHF.	DK

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
Inerta 10 mg lágy kapszula	DK/H/2242/001	OGYI-T-22560/01	ACTAVIS GROUP PTC EHF.	HU
ISOTRETINOIN ACTAVIS 10 MG KAPSLAR, MJUKA	DK/H/2242/001	48555	ACTAVIS GROUP PTC EHF.	SE
ISOTRETINOIN ACTAVIS 10 MG MÁKKÉ KAPSULY	DK/H/2242/001	46/0418/13-S	ACTAVIS GROUP PTC EHF.	SK
ACNENOR, BLØDE KAPSLER	DK/H/2242/002	51480	ACTAVIS GROUP PTC EHF.	DK
Inerta 20 mg lágy kapszula	DK/H/2242/002	OGYI-T-22560/06-10	ACTAVIS GROUP PTC EHF.	HU
ISOTRETINOIN ACTAVIS 20 MG KAPSLAR, MJUKA	DK/H/2242/002	48556	ACTAVIS GROUP PTC EHF.	SE
ISOTRETINOIN ACTAVIS 20 MG MÁKKÉ KAPSULY	DK/H/2242/002	46/0419/13-S	ACTAVIS GROUP PTC EHF.	SK
Pharmiso	DK/H/0300/002	31478	HEXAL AG	DK
Isotret-Hexal 20 mg Kapseln	DK/H/0300/002	54100.01.00	HEXAL AG	DE
Isotret-HEXAL 10 mg Kapseln	DK/H/0300/001	54100.00.00	HEXAL AG	DE
ISOTRETINOÏNE SANDOZ 20 MG, CAPSULES	NL/H/0593/002	RVG 26548	SANDOZ B.V.	NL
ISOTRETINOÏNE SANDOZ 10 MG, CAPSULES	NL/H/0593/001	RVG 26547	SANDOZ B.V.	NL
Accutin	not available	31531	SANDOZ A/S	DK
Accutin	not available	31532	SANDOZ A/S	DK
Pharmiso	DK/H/0300/001	31477	HEXAL AG	DK

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
Isotretinoïne Sandoz 20 mg zachte capsules	NL/H/0593/002	BE291137	SANDOZ N.V.	BE
Isotretinoin 10 mg Capsules	NL/H/0593/001	PL 04416/1032	SANDOZ LTD	UK
Isotretinoin 20 mg Capsules	NL/H/0593/002	PL 04416/1033	SANDOZ LTD	UK
Tretin 10mg , καψάκια μαλακά	not available	66320/14/07-01-2015	TARGET PHARMA SINGLE MEMBER PRIVATE LTD	GR
Tretin 20mg, καψάκια μαλακά	not available	85176/14/07-01-2015	TARGET PHARMA SINGLE MEMBER PRIVATE LTD	GR
Isotretinoin PUREN 10 mg Weichkapseln	PT/H/1878/001	54253.00.00	PUREN PHARMA GMBH & CO. KG	DE
Isotretinoin PUREN 20 mg Weichkapseln	PT/H/1878/002	54253.01.00	PUREN PHARMA GMBH & CO. KG	DE
Isotretinoïne Aurobindo 10 mg, capsules	PT/H/1878/001-002	RVG 27577	AUROBINDO PHARMA B.V.	NL
Isotretinoïne Aurobindo 20 mg, capsules	PT/H/1878/001-002	RVG 27578	AUROBINDO PHARMA B.V.	NL
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057584	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057683	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057782	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057881	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057980	AUROVITAS UNIPessoal, LDA.	PT

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
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058087	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058186	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058285	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058384	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058483	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	PT/H/1878/002	AUROVITAS UNIPessoal, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	PT/H/1878/001	AUROVITAS UNIPessoal, LDA.	PT
Accuran, 10 mg/cap, καψάκιο, μαλακό	not available	18066/21-03-2012	NEXUS MEDICALS S.A.	GR
Accuran, 20 mg/cap, καψάκιο, μαλακό	not available	18066/21-03-2012	NEXUS MEDICALS S.A.	GR
ACNOGEN/GENEPHARM	not available	38591/10/18-04-2011	GENEPHARM S.A.	GR
ACNOGEN/GENEPHARM	not available	38594/10/18-04-2011	GENEPHARM S.A.	GR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 129 1 9	SAS PIERRE FABRE DERMATOLOGIE	FR
ISOCURAL 10 mg, zachte capsules	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX S.A.	BE
ISOACNÉ 10 mg cápsulas blandas	FR/H/0250/002	67.570	PIERRE FABRE IBERICA / SPAIN	ES

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
ISORAC 10 mg, capsule molli	FR/H/0250/002	037551025	PIERRE FABRE ITALIA S.P.A.	IT
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	1128/09020250	PIERRE FABRE DERMATOLOGIE	LU
Curacne 10 mg Kapsulki miekkie	FR/H/0250/002	11919	PIERRE FABRE DERMATOLOGIE	PL
Isotretinoína Pierre Fabre 10 mg cápsulas moles	FR/H/0250/002	5732482	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 115 0 9	SAS PIERRE FABRE DERMATOLOGIE	FR
ISOCURAL 20 mg, capsules molles	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX S.A.	BE
ISOACNÉ 20 mg cápsulas blandas	FR/H/0250/003	67.571	PIERRE FABRE IBERICA / SPAIN	ES
ISORAC 20 mg, capsule molli	FR/H/0250/003	037551076	PIERRE FABRE ITALIA S.P.A.	IT
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	1128/09020249	PIERRE FABRE DERMATOLOGIE	LU
Curacne 20 mg Kapsulki miekkie	FR/H/0250/003	11918	PIERRE FABRE DERMATOLOGIE	PL
Isotretinoína Pierre Fabre 20 mg cápsulas moles	FR/H/0250/003	5732987	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
CURACNÉ 40 mg, capsule molle	FR/H/0250/004	367 603-4	SAS PIERRE FABRE DERMATOLOGIE	FR
ISOCURAL 40 mg, capsules molles	FR/H/0250/004	BE 334047	PIERRE FABRE BENELUX S.A.	BE

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
ISOACNÉ 40 mg cápsulas blandas	FR/H/0250/004	69.927	PIERRE FABRE IBERICA / SPAIN	ES
CURACNÉ 40 mg, capsule molle	FR/H/0250/004	1128/08010002	PIERRE FABRE DERMATOLOGIE	LU
Curacne 40 mg Kapsułki miękkie	FR/H/0250/004	14709	PIERRE FABRE DERMATOLOGIE	PL
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 123 3 9	SAS PIERRE FABRE DERMATOLOGIE	FR
ISOCURAL 5 mg, capsules molles	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX S.A.	BE
ISOACNÉ 5 mg cápsulas blandas	FR/H/0250/001	67.464	PIERRE FABRE IBERICA / SPAIN	ES
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	1128/09020251	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ 40 mg mäkké kapsuly	FR/H/0250/001	11920	PIERRE FABRE DERMATOLOGIE	PL
Isotretinoína Pierre Fabre 5 mg, cápsulas moles	FR/H/0250/001	5731989	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
ISOCURAL 10 mg, capsules molles	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX S.A.	BE
ISOCURAL 20 mg, zachte capsules	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX S.A.	BE
ISOCURAL 40 mg, zachte capsules	FR/H/0250/004	BE334047	PIERRE FABRE BENELUX S.A.	BE
ISOCURAL 5 mg, zachte capsules	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX S.A.	BE

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
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 131 6 9	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 134 5 9	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 132 2 0	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 133 9 8	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 135 1 0	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 136 8 8	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 157 5 0	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 158 1 1	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 125 6 8	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 126 2 9	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 127 9 7	SAS PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 128 5 8	SAS PIERRE FABRE DERMATOLOGIE	FR
Isotretinoína Pierre Fabre 10 mg cápsulas moles	FR/H/0250/002	5732581	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT

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
Isotretinoína Pierre Fabre 10 mg cápsulas moles	FR/H/0250/002	5732680	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 10 mg cápsulas moles	FR/H/0250/002	5732789	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 10 mg cápsulas moles	FR/H/0250/002	5732888	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 20 mg cápsulas moles	FR/H/0250/003	5733084	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 20 mg cápsulas moles	FR/H/0250/003	5733183	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 20 mg cápsulas moles	FR/H/0250/003	5733282	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 20 mg cápsulas moles	FR/H/0250/003	5733381	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 5 mg, cápsulas moles	FR/H/0250/001	5732086	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 5 mg, cápsulas moles	FR/H/0250/001	5732185	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT

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
Isotretinoína Pierre Fabre 5 mg, cápsulas moles	FR/H/0250/001	5732284	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
Isotretinoína Pierre Fabre 5 mg, cápsulas moles	FR/H/0250/001	5732383	PIERRE FABRE DERMO-COSMETIQUE PORTUGAL, LDA	PT
CURACNÉ 10 mg měkká tobolka	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkká tobolka	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 40 mg, měkká tobolka	FR/H/0250/004	46/095/08-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 40 mg mäkké kapsuly	FR/H/0250/004	46/0119/08-S	SAS PIERRE FABRE DERMATOLOGIE	SK
Ciscutan 30 mg – Kapseln	not available	135651	PELPHARMA HANDELS GMBH	AT
AISOSKIN 10 mg capsule molli	not available	035258019	FIDIA FARMACEUTICI S.P.A	IT
AISOSKIN 20 mg capsule molli	not available	035258021	FIDIA FARMACEUTICI S.P.A	IT
Isdiben 10 mg cápsulas blandas	UK/H/0504/002	66.121	ISDIN, S.A.	ES
Isdiben 20 mg cápsulas blandas	UK/H/0504/003	66.122	ISDIN, S.A.	ES
Isotretinoïne Mylan 10 mg, zachte capsules	UK/H/0504/002	RVG 27573	MYLAN B.V.	NL
Isotretinoïne Mylan 20 mg, zachte capsules	UK/H/0504/003	RVG 27574	MYLAN B.V.	NL

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
Isotretinoin 10 mg Soft Capsules	UK/H/0504/002	PL 04569/0725	GENERICS [UK] LIMITED	UK
Isotretinoin 20 mg Soft Capsules	UK/H/0504/003	PL 04569/0724	GENERICS [UK] LIMITED	UK
Isotretinoin 5 mg Soft Capsules	UK/H/0504/001	PL 04569/0726	GENERICS [UK] LIMITED	UK
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/05	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/04	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/10	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/06	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/02	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/07	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/01	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/03	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/09	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/08	TEVA MAGYARORSZÁG ZRT	HU
Ciscutan 40 mg – Kapseln	not available	1-27652	PELPHARMA HANDELS GMBH	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
MAYESTA 10 mg cápsulas blandas	not available	69.571	ALFASIGMA ESPAÑA, S.L.	ES
MAYESTA 20 mg cápsulas blandas	not available	69.572	ALFASIGMA ESPAÑA, S.L.	ES
Isoderm 10 mg	not available	48903.00.00	DERMAPHARM AG	DE
Isoderm 20 mg	not available	48903.01.00	DERMAPHARM AG	DE
Isoderm, 10 mg, kapsułki, miękkie	not available	18136	SUN-FARM SP. Z.O.O.	PL
Isoderm, 20 mg, kapsulki, miekkie	not available	18137	SUN-FARM SP. Z.O.O.	PL
Ciscutan 5 mg – Kapseln	not available	1-29997	PELPHARMA HANDELS GMBH	AT
Isotretinoin ratiopharm 20 mg mjúk hylki	DK/H/0298/002	IS/1/14/036/01	RATIOPHARM GMBH	IS
Isotretinoin ratiopharm 20 mg kapsel, mjuk	DK/H/0298/001	17152	RATIOPHARM GMBH	FI
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001	036083018	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001	036083020	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001	036083032	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001	036083044	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001-002	036083057/M	DIFA COOPER S.P.A.	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
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083069/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083071/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083083/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083095/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083107/M	DIFA COOPER S.P.A.	IT
Isotretinoin „ratiopharm“ 20 mg – Kapseln	DK/H/0298/002	1-24649	RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH	AT
Isotretinoin-ratiopharm® 20 mg Weichkapseln	DK/H/0298/002	54096.01.00	RATIOPHARM GMBH	DE
Isotretinoin-ratiopharm® 10 mg Weichkapseln	DK/H/0298/001	54096.00.00	RATIOPHARM GMBH	DE
Isotretinoin „ratiopharm“ 10 mg – Kapseln	DK/H/0298/001	1-24648	RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH	AT
Isotretinoin ratiopharm 20 mg kapseli, pehmeä	DK/H/0298/001	17152	RATIOPHARM GMBH	FI
Isotretinoin "ratiopharm", bløde kapsler	DK/H/0298/001	31473	RATIOPHARM GMBH	DK
Isotretinoin "ratiopharm", bløde kapsler	DK/H/0298/002	31474	RATIOPHARM GMBH	DK
Decutan 10 mg hylki, mjúk	DK/H/0368/001	IS/1/02/035/01	ACTAVIS HF.	IS

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
Decutan 20 mg hylki, mjúk	DK/H/0368/002	IS/1/02/035/02	ACTAVIS HF.	IS
ISOMACNE, BLØDE KAPSLER	DK/H/0368/002	33137	ACTAVIS GROUP PTC EHF.	DK
ISOMACNE, BLØDE KAPSLER	DK/H/0368/001	33136	ACTAVIS GROUP PTC EHF.	DK
Decutan 10mg Soft Capsules	not available	MA155/00501	ACTAVIS GROUP HF.	MT
Decutan 20mg Soft Capsules	not available	MA155/00502	ACTAVIS GROUP HF.	MT
Isotretinoin Orifarm 10 mg kapslar, mjuka	DK/H/1060/001	47763	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	47764	ORIFARM GENERICS A/S	SE
Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/001	34484	ORIFARM GENERICS A/S	DK
Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/002	34485	ORIFARM GENERICS A/S	DK
Isotretinoin Orifarm 10 mg kapsler, myke	DK/H/1060/001	07-5310	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 20 mg kapsler, myke	DK/H/1060/002	07-5311	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
IsoGalen® 20 mg Weichkapseln	DK/H/1060/001	71369.00.00	GALENPHARMA GMBH	DE
IsoGalen® 10 mg Weichkapseln	DK/H/1060/002	71368.00.00	GALENPHARMA GMBH	DE

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
Rizuderm 5mg Capsules	not available	PL 16853/0132	ALLIANCE PHARMACEUTICALS LTD	UK
Isotretinoin 20mg Capsules	not available	PL 16853/0133	ALLIANCE PHARMACEUTICALS LTD	UK
Isotretinoin 5mg Capsules	not available	PL 16853/0132	ALLIANCE PHARMACEUTICALS LTD	UK
Rizuderm 20mg Capsules	not available	PL 16853/0133	ALLIANCE PHARMACEUTICALS LTD	UK
A-CNOTREN 10 mg καψάκια	DK/H/0889/001	45/16-01-2012	PHARMATHEN HELLAS S.A.	GR
A-cnotren	not available	45047/10/18-04-2012	PHARMATHEN HELLAS S.A.	GR
FLEXRESAN 10 mg cápsulas blandas	not available	66.160	ESPECIALIDADES FARMACEUTICAS CENTRUM, S.A	ES
Axotret 10 mg, kapsułki, miękkie	not available	11318	AXXON SP. Z O.O.	PL
Axotret 20 mg, kapsułki, miękkie	not available	11319	AXXON SP. Z O.O.	PL
Roaccutane 10 mg zachte capsules	UK/H/666/01	BE130611	N.V. ROCHE S.A.	BE
Roaccutane 10 mg Weichkapseln	UK/H/666/01	BE130611	N.V. ROCHE S.A.	BE
Roaccutane 20 mg zachte capsules	UK/H/666/02	BE130627	N.V. ROCHE S.A.	BE
Roaccutane 20 mg Weichkapseln	UK/H/666/02	BE130627	N.V. ROCHE S.A.	BE
Roaccutan 10 mg pehmeät kapselit	UK/H/0666/001	9220	ROCHE OY	FI

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
Roaccutan 20 mg mjuka kapslar	UK/H/0666/002	9221	ROCHE OY	FI
Roaccutane 10 mg soft capsules	UK/H/0666/001	PL 00031/0617	ROCHE PRODUCTS LTD	UK
Roaccutane 20 mg soft capsules	UK/H/0666/002	PL 00031/0160	ROCHE PRODUCTS LTD	UK
Roaccutane 10 mg Soft Capsules	UK/H/0666/001	PA50/53/5	ROCHE PRODUCTS LTD	IE
Roaccutane 20 mg Soft Capsules	UK/H/0666/002	PA50/53/4	ROCHE PRODUCTS LTD	IE
Roaccutane 10 mg Weichkapseln	UK-H-666	0178/10010651	N.V. ROCHE S.A.	LU
Roaccutane 20 mg Weichkapseln	UK-H-666	0178/10040736	N.V. ROCHE S.A.	LU
Roaccutane 10 mg mehke kapsule	UK/H/0666/001	H/96/01368/002	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg mehke kapsule	UK/H/0666/001	H/96/01368/003	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	UK/H/0666/002	H/96/01368/007	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	UK/H/0666/002	H/96/01368/008	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg mehke kapsule	UK/H/0666/001	H/96/01368/004	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	UK/H/0666/002	H/96/01368/006	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg, pehmekapslid	NL/H/666/002	404002	ROCHE EESTI OÜ	EE

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
Roaccutane 10 mg, pehmekapslid	UK/H/0666/001	052294	ROCHE EESTI OÜ	EE
Roaccutane 10 mg capsules molles	UK/H/0666/001	0178/10010651	N.V. ROCHE S.A.	LU
Roaccutane 20 mg capsules molles	UK/H/0666/002	0178/10040736	N.V. ROCHE S.A.	LU
Roaccutan 10 mg pehmeät kapselit	UK/H/0666/001	9220	ROCHE OY	FI
Roaccutan 20 mg pehmeät kapselit	UK/H/0666/002	9221	ROCHE OY	FI
Roaccutane 20 mg capsules molles	UK/H/666/02	BE130627	N.V. ROCHE S.A.	BE
Roaccutane 10 mg capsules molles	UK/H/666/01	BE130611	N.V. ROCHE S.A.	BE
Roaccutan 10 mg lágy kapszula	UK/H/0666/001	OGYI-T-1278/01	ROCHE (MAGYARORSZÁG) KFT	HU
Roaccutan 20 mg lágy kapszula	UK/H/0666/002	OGYI-T-1278/02	ROCHE (MAGYARORSZÁG) KFT	HU
Roaccutane 20 mg mäkké kapsuly	UK/H/0666/002	46/0361/05-S	ROCHE SLOVENSKO S.R.O.	SK
Roaccutane 10 mg mäkké kapsuly	UK/H/0666/001	46/0360/05-S	ROCHE SLOVENSKO S.R.O.	SK
Roaccutane 10 mg mehke kapsule	UK/H/666/001	H/96/01368/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	UK/H/666/002	H/96/01368/005	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg minkštosios kapsulės	UK/H/0666/001	LT/1/05/0406/003	UAB "ROCHE LIETUVA"	LT

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
Roaccutane 10 mg minkštosios kapsulės	UK/H/0666/001	LT/1/05/0406/001	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštosios kapsulės	UK/H/0666/002	LT/1/05/0406/006	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg mīkstās kapsulas	UK/H/0666/001	05-0517	ROCHE LATVIJA SIA	LV
Roaccutane 10 mg minkštosios kapsulės	UK/H/0666/001	LT/1/05/0406/004	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštosios kapsulės	UK/H/0666/002	LT/1/05/0406/008	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštosios kapsulės	UK/H/0666/002	LT/1/05/0406/007	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg mīkstās kapsulas	UK/H/0666/002	05-0518	ROCHE LATVIJA SIA	LV
Roaccutane 20 mg minkštosios kapsulės	UK/H/0666/002	LT/1/05/0406/005	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštosios kapsulės	UK/H/0666/001	LT/1/05/0406/002	UAB "ROCHE LIETUVA"	LT
Sotret 10 mg capsule moi	not available	6765/2014/01	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	not available	6766/2014/01	TERAPIA S.A.	RO
Sotret 20 mg lágy kapszula	not available	OGYI-T-8989/07	TERAPIA S.A.	HU
Sotret 20 mg lágy kapszula	not available	OGYI-T-8989/06	TERAPIA S.A.	HU
Sotret 20 mg lágy kapszula	not available	OGYI-T-8989/05	TERAPIA S.A.	HU

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
Sotret 10 mg lágy kapszula	not available	OGYI-T-8989/01	TERAPIA S.A.	HU
Sotret 20 mg lágy kapszula	not available	OGYI-T-8989/08	TERAPIA S.A.	HU
Sotret 10 mg lágy kapszula	not available	OGYI-T-8989/02	TERAPIA S.A.	HU
Sotret 10 mg lágy kapszula	not available	OGYI-T-8989/04	TERAPIA S.A.	HU
Sotret 10 mg lágy kapszula	not available	OGYI-T-8989/03	TERAPIA S.A.	HU
ISOTRETINOIN "ACTAVIS", BLØDE KAPSLER 40 MG	DK/H/1747/001	37461	ACTAVIS GROUP PTC EHF.	DK
ISOTRETINOIN ACTAVIS 40 MG, KAPSELI, PEHMEÄ	DK/H/1747/001	27968	ACTAVIS GROUP PTC EHF.	FI
Isotretinoïne 10 PCH, capsules 10 mg	NL/H/902/001	RVG 27575	PHARMACHEMIE B.V	NL
ISOSUPRA LIDOSE 8 mg, gélules	not available	BE266533	LABORATOIRES SMB S.A.	BE
ISOSUPRA LIDOSE 8 mg, capsules, hard	not available	BE266533	LABORATOIRES SMB S.A.	BE
Isosupra Lidose 8 mg Hartkapsel	not available	BE 266533	LABORATOIRES SMB S.A.	BE
ISOSUPRA LIDOSE 16 mg, gélules	not available	BE266542	LABORATOIRES SMB S.A.	BE
Isosupra Lidose 16 mg, capsules, hard	not available	BE266542	LABORATOIRES SMB S.A.	BE
Isosupra Lidose 16 mg Hartkapsel	not available	BE 266542	LABORATOIRES SMB S.A.	BE

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
FLEXRESAN 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACEUTICAS CENTRUM, S.A	ES
PROCUTA 5 mg, capsule molle	not available	34009 358 110 9 7	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 5 mg, capsule molle	not available	34009 357 840 3 2	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 5 mg, capsule molle	not available	34009 358 111 5 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 5 mg, capsule molle	not available	34009 358 112 1 9	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 5 mg, capsule molle	not available	34009 357 842 6 1	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 358 107 8 6	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 357 838 9 9	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 358 108 4 7	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 358 109 0 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 357 839 5 0	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 104 9 6	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 357 836 6 0	LABORATOIRES EXPANSCIENCE	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
PROCUTA 20 mg, capsule molle	not available	34009 358 105 5 7	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 106 1 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 357 837 2 1	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 40 mg, capsule molle	not available	34009 367 880 8 4	LABORATOIRES EXPANSCIENCE	FR