



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2023
EMA/550356/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): isotretinoin (oral formulations)

Procedure No. PSUSA/00010488/202305



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® 10 mg Weichkapseln	not available	141456	ALMIRALL HERMAL GMBH	AT
Aknenormin® 20 mg Weichkapseln	not available	141457	ALMIRALL HERMAL GMBH	AT
Aknenormin® 40 mg Weichkapseln	not available	141458	ALMIRALL HERMAL GMBH	AT
Aknenormin® 5 mg Weichkapseln	not available	141455	ALMIRALL HERMAL GMBH	AT
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
Ciscutan 30 mg – Kapseln	not available	135651	PELPHARMA HANDELS GMBH	AT
Ciscutan 40 mg – Kapseln	not available	1-27652	PELPHARMA HANDELS GMBH	AT
Ciscutan 5 mg – Kapseln	not available	1-29997	PELPHARMA HANDELS GMBH	AT
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	141358	LABORATOIRES BAILLEUL SA	AT
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	141360	LABORATOIRES BAILLEUL SA	AT
Isotiorga 40 mg Weichkapseln	AT/H/1170/003	141362	LABORATOIRES BAILLEUL SA	AT
Isotretinoin GAP 10 mg Weichkapseln	AT/H/1017/002	140405	GAP S.A.	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
Isotretinoin GAP 20 mg Weichkapseln	AT/H/1017001-004DC	140406	GAP S.A.	AT
Isotretinoin GAP 40 mg Weichkapseln.	AT/H/1017/004	140407	GAP S.A.	AT
Isotretinoin GAP 5 mg Weichkapseln	AT/H/1017/001	140409	GAP S.A.	AT
ISOCURAL 10 mg, capsules molles	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	BE
ISOCURAL 10 mg, zachte capsules	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	BE
ISOCURAL 20 mg, capsules molles	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX	BE
ISOCURAL 20 mg, zachte capsules	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX	BE
ISOCURAL 40 mg, capsules molles	FR/H/0250/004	BE 334047	PIERRE FABRE BENELUX	BE
ISOCURAL 40 mg, zachte capsules	FR/H/0250/004	BE334047	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg, capsules molles	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg, zachte capsules	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE
Isosupra Lidose 16 mg Hartkapseln	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, gélules	not available	BE266542	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
Isosupra Lidose 8 mg Hartkapseln	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, gélules	not available	BE266533	LABORATOIRES SMB S.A.	BE
Isotiorga 10 mg capsules molles	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL SA	BE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL SA	BE
Isotiorga 10 mg zachte capsules	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL SA	BE
Isotiorga 20 mg capsules molles	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL SA	BE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL SA	BE
Isotiorga 20 mg zachte capsules	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL SA	BE
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	BE266296	EUROGENERICS N.V./S.A.	BE
Isotretinoïne EG 10 mg Weichkapseln	BE/H/0193/001	BE266296	EUROGENERICS N.V./S.A.	BE
Isotretinoïne EG 10 mg zachte capsules	BE/H/0193/001	BE266296	EUROGENERICS N.V./S.A.	BE
Isotrétinoïne EG 20 mg capsules molles	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

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Isotretinoïne EG 20 mg zachte capsules	BE/H/0193/002	BE270173	EUROGENERICS N.V./S.A.	BE
Roaccutane 10 mg capsules molles	EE/H/0271/001	BE130611	N.V. ROCHE S.A.	BE
Roaccutane 10 mg Weichkapseln	EE/H/0271/001	BE130611	N.V. ROCHE S.A.	BE
Roaccutane 10 mg zachte capsules	EE/H/0271/001	BE130611	N.V. ROCHE S.A.	BE
Roaccutane 20 mg capsules molles	EE/H/0271/002	BE130627	N.V. ROCHE S.A.	BE
Roaccutane 20 mg Weichkapseln	EE/H/0271/002	BE130627	N.V. ROCHE S.A.	BE
Roaccutane 20 mg zachte capsules	EE/H/0271/002	BE130627	N.V. ROCHE S.A.	BE
Роакутан 20 mg капсули, меки	not available	20030084	ROCHE BULGARIA EOOD	BG
Acmotren 10mg soft gelatin capsules	not available	20320	SAPIENS PHARMACEUTICALS LTD	CY
Acmotren 20mg soft gelatin capsules	not available	20321	SAPIENS PHARMACEUTICALS LTD	CY
Isotroin 30 mg καψάκιο, μαλακό	not available	023420	IASIS PHARMA	CY
ISOTROIN® 10mg καψάκια μαλακά	not available	20695	IASIS PHARMA	CY
ISOTROIN® 20mg καψάκια μαλακά	not available	20693	IASIS PHARMA	CY
Aknenormin 10 mg měkké tobolky	DE/H/1702/001	46/138/05-C	ALMIRALL HERMAL GMBH	CZ

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 měkké tobolky	DE/H/1702/002	46/139/05-C	ALMIRALL HERMAL GMBH	CZ
Asotiorga 20 mg měkké tobolky	AT/H/1170/002	46/491/20-C	LABORATOIRES BAILLEUL SA	CZ
CURACNÉ 10 mg měkké tobolky	FR/H/0250/002	46/056/06-C	PIERRE FABRE MEDICAMENT	CZ
CURACNÉ 20 mg měkké tobolky	FR/H/0250/003	46/054/06-C	PIERRE FABRE MEDICAMENT	CZ
CURACNÉ 40 mg měkké tobolky	FR/H/0250/004	46/095/08-C	PIERRE FABRE MEDICAMENT	CZ
Isotretinoin Belupo 10 mg měkké tobolky	not available	46/665/15-C	BELUPO, S.R.O.	CZ
Isotretinoin Belupo 20 mg měkké tobolky	not available	46/666/15-C	BELUPO, S.R.O.	CZ
Aknenormin 10 mg Weichkapseln	DE/H/1702/001	55003.00.00	ALMIRALL HERMAL GMBH	DE
Aknenormin 20 mg Weichkapseln	DE/H/1702/002	55003.01.00	ALMIRALL HERMAL GMBH	DE
IsoGalen® 10 mg Weichkapseln	DK/H/1060/002	71368.00.00	GALENPHARMA GMBH	DE
IsoGalen® 20 mg Weichkapseln	DK/H/1060/001	71369.00.00	GALENPHARMA GMBH	DE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	7003560.00.00	LABORATOIRES BAILLEUL SA	DE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	7003561.00.00	LABORATOIRES BAILLEUL SA	DE
Isotret-HEXAL 10 mg Kapseln, Weichkapseln	DK/H/0300/001	54100.00.00	HEXAL AG	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
Isotret-HEXAL 20 mg Kapseln, Weichkapseln	DK/H/0300/002	54100.01.00	HEXAL AG	DE
Isotretinoin Basics 10 mg Weichkapseln	NL/H/3739/001	97279.00.00	BASICS GMBH	DE
Isotretinoin Basics 20 mg Weichkapseln	NL/H/3739/002	97280.00.00	BASICS GMBH	DE
Isotretinoin GAP 10 mg Weichkapseln	AT/H/1017/002	2204130.00.00	GAP S.A.	DE
Isotretinoin GAP 20 mg Weichkapseln	AT/H/1017/003	2204131.00.00	GAP S.A.	DE
Isotretinoin-ratiopharm® 10 mg Weichkapseln	DK/H/0298/001	54096.00.00	RATIOPHARM GMBH	DE
Isotretinoin-ratiopharm® 20 mg Weichkapseln	DK/H/0298/002	54096.01.00	RATIOPHARM GMBH	DE
ACNENOR, BLØDE KAPSLER	DK/H/2242/001	51479	TEVA B.V	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/002	51480	TEVA B.V	DK
Isomacne, soft capsules	DK/H/0368/002	33137	TEVA B.V	DK
Isomacne, soft capsules	DK/H/0368/001	33136	TEVA B.V	DK
Isotracin, bløde kapsler	AT/H/1017/002	62518	2CARE4 GENERICS APS	DK
Isotracin, bløde kapsler	AT/H/1017/003	62519	2CARE4 GENERICS APS	DK
Isotretinoin "Difa", bløde kapsler	DK/H/2687/001	58419	DIFA COOPER S.P.A.	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
Isotretinoin "Difa", bløde kapsler	DK/H/2687/002	58420	DIFA COOPER S.P.A.	DK
Isotretinoin "Difa", bløde kapsler	DK/H/2687/003	58421	DIFA COOPER S.P.A.	DK
Isotretinoin "Difa", bløde kapsler	DK/H/2687/004	58422	DIFA COOPER S.P.A.	DK
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 "Orion", bløde kapsler	DK/H/0889/002	34933	PHARMATHEN S.A.	DK
Isotretinoin "Orion", bløde kapsler	DK/H/0889/001	34932	PHARMATHEN S.A.	DK
Isotretinoin "Sandoz", bløde kapsler	NL/H/4820/001	62364	SANDOZ A/S	DK
Isotretinoin "Sandoz", bløde kapsler	NL/H/4820/002	62365	SANDOZ A/S	DK
Isotretinoin "Sandoz", bløde kapsler	NL/H/4820/003	62366	SANDOZ A/S	DK
Isotretinoin "Teva", bløde kapsler	DK/H/0298/001	31473	TEVA B.V	DK
Isotretinoin "Teva", bløde kapsler	DK/H/0298/002	31474	TEVA B.V	DK
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

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 "Difa Cooper", bløde kapsler	DK/H/1749/001	37463	DIFA COOPER S.P.A.	DK
Pharmiso, bløde kapsler	DK/H/0300/002	31478	HEXAL AG	DK
Pharmiso, bløde kapsler	DK/H/0300/001	31477	HEXAL AG	DK
Isotiorga, 20 mg pehmekapslid	AT/H/1170/002	1058322	LABORATOIRES BAILLEUL SA	EE
Isotretinoin Sandoz 10 mg pehmekapslid	NL/H/4820/002	1006120	SANDOZ PHARMACEUTICALS D.D.	EE
Isotretinoin Sandoz 20 mg pehmekapslid	NL/H/4820/003	1006220	SANDOZ PHARMACEUTICALS D.D.	EE
Isotretinoin Sandoz 5 mg pehmekapslid	NL/H/4820/001	1006020	SANDOZ PHARMACEUTICALS D.D.	EE
Roaccutane 10 mg, pehmekapslid	EE/H/0271/001	052294	ROCHE EESTI OÜ	EE
Roaccutane 20 mg, pehmekapslid	EE/H/0271/002	404002	ROCHE EESTI OÜ	EE
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
Acnisdin 10 mg cápsulas blandas EFG	AT/H/1017/002	85584	ISDIN, S.A.	ES
Acnisdin 20 mg cápsulas blandas EFG	AT/H/1017/003	85585	ISDIN, S.A.	ES
Acnisdin 40 mg cápsulas blandas	AT/H/1017/004	85748	ISDIN, S.A.	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
Dercutane 10 mg cápsulas blandas	not available	65.333	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Dercutane 20 mg cápsulas blandas	not available	65.334	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Dercutane 30 mg cápsulas blandas	not available	78.326	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Dercutane 40 mg cápsulas blandas	not available	67.878	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Dercutane 5 mg cápsulas blandas	not available	69.742	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Flexresan 10 mg cápsulas blandas	not available	66.160	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 10 mg cápsulas blandas	not available	66.160	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Isdiben 10 mg cápsulas blandas	NL/H/4813/001	66.121	ISDIN, S.A.	ES
Isdiben 20 mg cápsulas blandas	NL/H/4813/002	66.122	ISDIN, S.A.	ES
Isdiben 40 mg cápsulas blandas	IT/H/0739/004	76.045	ISDIN, S.A.	ES
ISOACNÉ 10 mg cápsulas blandas	FR/H/0250/002	67.570	PIERRE FABRE IBERICA, S.A.	ES
ISOACNÉ 20 mg cápsulas blandas	FR/H/0250/003	67.571	PIERRE FABRE IBERICA, S.A.	ES
ISOACNÉ 40 mg cápsulas blandas	FR/H/0250/004	69.927	PIERRE FABRE IBERICA, S.A.	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
ISOACNÉ 5 mg cápsulas blandas	FR/H/0250/001	67.464	PIERRE FABRE IBERICA, S.A.	ES
Isotiorga 20 mg cápsulas blandas EFG	AT/H/1170/002	86648	LABORATOIRES BAILLEUL SA	ES
Isotiorga 40 mg cápsulas blandas	AT/H/1170/003	86649	LABORATOIRES BAILLEUL SA	ES
Isotretinoína SUN 20 mg cápsulas blandas EFG	NL/H/3739/002	82567	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES
Isotretinoína SUN10 mg cápsulas blandas EFG	NL/H/3739/001	82566	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES
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
Isotracin 10 mg mjuka kapslar.	AT/H/1017/002	36975	2CARE4 GENERICS APS	FI
Isotracin 10 mg pehmeät kapselit.	AT/H/1017/002	36975	2CARE4 GENERICS APS	FI
Isotracin 20 mg mjuka kapslar.	AT/H/1017/003	36976	2CARE4 GENERICS APS	FI
Isotracin 20 mg pehmeät kapselit.	AT/H/1017/003	36976	2CARE4 GENERICS APS	FI
Isotretinoin Actavis 10 mg mjuk kapsel	DK/H/0297/001	17179	ACTAVIS GROUP PTC EHF.	FI
Isotretinoin Actavis 10 mg, kapseli, pehmeä	DK/H/0297/001	17179	ACTAVIS GROUP PTC EHF.	FI
Isotretinoin Actavis 20 mg mjuk kapsel	DK/H/0297/002	17180	ACTAVIS GROUP PTC EHF.	FI

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Isotretinoin Actavis 20 mg, kapseli, pehmeä	DK/H/0297/002	17180	ACTAVIS GROUP PTC EHF.	FI
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orion 20 mg pehmeat kapselit	DK/H/0889/002	21907	PHARMATHEN S.A.	FI
CONTRACNE 10 mg, capsule molle	not available	34009 358 120 4 9	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 10 mg, capsule molle	not available	34009 358 121 0 0	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 10 mg, capsule molle	not available	34009 358 122 7 8	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 116 7 7	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 117 3 8	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 119 6 7	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 40 mg, capsule molle	not available	34009 367 884 3 5	LABORATOIRES BAILLEUL SA	FR
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
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 129 1 9	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 131 6 9	PIERRE FABRE MEDICAMENT	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
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 134 5 9	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 132 2 0	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 133 9 8	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 115 0 9	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 135 1 0	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 136 8 8	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 157 5 0	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 158 1 1	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 40 mg, capsule molle	FR/H/0250/004	34009 367 603 4 9	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 123 3 9	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 125 6 8	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 126 2 9	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 127 9 7	PIERRE FABRE MEDICAMENT	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 128 5 8	PIERRE FABRE MEDICAMENT	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
ISOTRETINOINE ACNETRAIT 10 mg, capsule molle	not available	NL 26226	ARROW GENERIQUES	FR
ISOTRETINOINE ACNETRAIT 20 mg, capsule molle	not available	NL 26227	ARROW GENERIQUES	FR
ISOTRETINOINE ACNETRAIT 40 mg, capsule molle	not available	NL 36266	ARROW GENERIQUES	FR
ISOTRETINOINE ACNETRAIT 5 mg, capsule molle	not available	NL 36265	ARROW GENERIQUES	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
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

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 357 837 2 1	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 40 mg, capsule molle	not available	34009 367 880 8 4	LABORATOIRES EXPANSCIENCE	FR
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
A-CNOTREN 10 mg καψάκια, μαλακά	DK/H/0889/001	45/16-01-2012	PHARMATHEN INVESTMENTS GROUP LIMITED	GR
A-CNOTREN 20 mg καψάκια, μαλακά	not available	45047/10/18-04-2012	PHARMATHEN INVESTMENTS GROUP LIMITED	GR
Isotretinoin/Bailleul 20 mg καψάκια, μαλακά	AT/H/1170/002	51520/25-05-2022	LABORATOIRES BAILLEUL SA	GR
Isotretinoin/Bailleul 40 mg καψάκια, μαλακά	AT/H/1170/003	51521/25-05-2022	LABORATOIRES BAILLEUL SA	GR
ISOTROIN 20 mg καψάκιο, μαλακό	not available	76449/10-11-11	IASIS PHARMA	GR
Isotroin 30 mg καψάκιο, μαλακό	not available	104547/02-11-20	IASIS PHARMA	GR
ISOTROIN® 10 mg καψάκιο, μαλακό	not available	76447/10-11-11	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® 40 mg καψάκιο, μαλακό	not available	78135/10-11-11	IASIS PHARMA	GR
REDUCAR 10mg μαλακό καψάκιο.	not available	32122/16/22-1-2018	GAP S.A.	GR
REDUCAR 20mg μαλακό καψάκιο.	not available	30565/16/22-1-2018	GAP S.A.	GR
Tretin 10 mg μαλακά καψάκια	not available	66320/14/07-01-2015	TARGET PHARMA SINGLE MEMBER PRIVATE LTD	GR
Tretin 20 mg μαλακά καψάκια	not available	85176/14/07-01-2015	TARGET PHARMA SINGLE MEMBER PRIVATE LTD	GR
Roaccutane 10 mg meke kapsule	not available	HR-H-462694255	ROCHE D.O.O.	HR
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 10 mg lágy kapszula	DK/H/2242/001	OGYI-T-22560/01	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

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 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
Inerta 20 mg lágy kapszula	DK/H/2242/002	OGYI-T-22560/06	ACTAVIS GROUP PTC EHF.	HU
Isotiorga 20 mg lágy kapszula	AT/H/1170/002	OGYI-T-24042/01	LABORATOIRES BAILLEUL SA	HU
Isotiorga 20 mg lágy kapszula	AT/H/1170/002	OGYI-T-24042/02	LABORATOIRES BAILLEUL SA	HU
Isotiorga 20 mg lágy kapszula	AT/H/1170/002	OGYI-T-24042/03	LABORATOIRES BAILLEUL SA	HU
Isotiorga 20 mg lágy kapszula	AT/H/1170/002	OGYI-T-24042/04	LABORATOIRES BAILLEUL SA	HU
Medinac 10 mg lágy kapszula	not available	OGYI-T-23225/01	MEDINER KFT.	HU
Medinac 10 mg lágy kapszula	not available	OGYI-T-23225/02	MEDINER KFT.	HU
Medinac 10 mg lágy kapszula	not available	OGYI-T-23225/03	MEDINER KFT.	HU
Medinac 10 mg lágy kapszula	not available	OGYI-T-23225/04	MEDINER KFT.	HU
Medinac 10 mg lágy kapszula	not available	OGYI-T-23225/05	MEDINER KFT.	HU
Medinac 20 mg lágy kapszula	not available	OGYI-T-23225/06	MEDINER KFT.	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
Medinac 20 mg lágy kapszula	not available	OGYI-T-23225/07	MEDINER KFT.	HU
Medinac 20 mg lágy kapszula	not available	OGYI-T-23225/08	MEDINER KFT.	HU
Medinac 20 mg lágy kapszula	not available	OGYI-T-23225/09	MEDINER KFT.	HU
Medinac 20 mg lágy kapszula	not available	OGYI-T-23225/10	MEDINER KFT.	HU
Roaccutan 10 mg lágy kapszula	EE/H/0271/001	OGYI-T-1278/01	ROCHE (MAGYARORSZÁG) KFT	HU
Roaccutan 20 mg lágy kapszula	EE/H/0271/002	OGYI-T-1278/02	ROCHE (MAGYARORSZÁG) KFT	HU
Sotret Neo 10 mg lágy kapszula	NL/H/3739/001	OGYI-T-23222 / 01	MEDICO UNO PHARMACEUTICALS SE	HU
Sotret Neo 20 mg lágy kapszula	NL/H/3739/002	OGYI-T-23222 / 02	MEDICO UNO PHARMACEUTICALS SE	HU
Isotretinoin 10 mg soft capsules	NL/H/4820/002	PA0711/312/002	ROWEX LTD	IE
Isotretinoin 20 mg soft capsules	NL/H/4820/003	PA0711/312/003	ROWEX LTD	IE
Isotretinoin GAP 10 mg capsule, soft	AT/H/1017/002	PA22735/002/001	GAP S.A.	IE
Isotretinoin GAP 20 mg capsule, soft	AT/H/1017/003	PA22735/002/002	GAP S.A.	IE
Isotretinoin SUN 10 mg soft capsules	NL/H/3739/001	PA2050/007/001	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IE
Isotretinoin SUN 20 mg soft capsules	NL/H/3739/002	PA2050/007/002	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IE

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 soft capsules	EE/H/0271/001	PA2307/007/001	ROCHE PRODUCTS (IRELAND) LIMITED	IE
Roaccutane 20 mg soft capsules	EE/H/0271/002	PA2307/007/002	ROCHE PRODUCTS (IRELAND) LIMITED	IE
Decutan 10 mg hylki, mjúk	DK/H/0368/001	IS/1/02/035/01	TEVA B.V	IS
Decutan 20 mg hylki, mjúk	DK/H/0368/002	IS/1/02/035/02	TEVA B.V	IS
Isotretinoin Alvogen 20 mg mjúk hylki	IS/H/0290/001	IS/1/14/036/01	ALVOGEN EHF	IS
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 capsule molli	IT/H/0739/002/DC	041853045	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	IT/H/0739/002/DC	041853058	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	IT/H/0739/002/DC	041853060	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	IT/H/0739/002/DC	041853045	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	IT/H/0739/002/DC	041853058	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	IT/H/0739/002/DC	041853060	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	IT/H/0739/003/DC	041853072	ISDIN S.R.L.	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
Isdiben 20 mg capsule molli	IT/H/0739/003/DC	041853084	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	IT/H/0739/003/DC	041853096	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	IT/H/0739/003/DC	041853072	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	IT/H/0739/003/DC	041853084	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	IT/H/0739/003/DC	041853096	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	IT/H/0739/004/DC	041853108	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	IT/H/0739/004/DC	041853110	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	IT/H/0739/004/DC	041853122	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	IT/H/0739/004/DC	041853108	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	IT/H/0739/004/DC	041853110	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	IT/H/0739/004/DC	041853122	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	IT/H/0739/001/DC	041853019	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	IT/H/0739/001/DC	041853021	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	IT/H/0739/001/DC	041853033	ISDIN S.R.L.	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
Isdiben 5 mg capsule molli	IT/H/0739/001/DC	041853019	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	IT/H/0739/001/DC	041853021	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	IT/H/0739/001/DC	041853033	ISDIN S.R.L.	IT
Isodifa 10 mg capsule molli	DK/H/2687/002	045513064	DIFA COOPER S.P.A.	IT
Isodifa 10 mg capsule molli	DK/H/2687/002	045513076	DIFA COOPER S.P.A.	IT
Isodifa 10 mg capsule molli	DK/H/2687/002	045513088	DIFA COOPER S.P.A.	IT
Isodifa 10 mg capsule molli	DK/H/2687/002	045513090	DIFA COOPER S.P.A.	IT
Isodifa 10 mg capsule molli	DK/H/2687/002	045513102	DIFA COOPER S.P.A.	IT
Isodifa 20 mg capsule molli	DK/H/2687/003	045513114	DIFA COOPER S.P.A.	IT
Isodifa 20 mg capsule molli	DK/H/2687/003	045513126	DIFA COOPER S.P.A.	IT
Isodifa 20 mg capsule molli	DK/H/2687/003	045513138	DIFA COOPER S.P.A.	IT
Isodifa 20 mg capsule molli	DK/H/2687/003	045513140	DIFA COOPER S.P.A.	IT
Isodifa 20 mg capsule molli	DK/H/2687/003	045513153	DIFA COOPER S.P.A.	IT
Isodifa 30 mg capsule molli	DK/H/2687/004	045513165	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
Isodifa 30 mg capsule molli	DK/H/2687/004	045513177	DIFA COOPER S.P.A.	IT
Isodifa 30 mg capsule molli	DK/H/2687/004	045513189	DIFA COOPER S.P.A.	IT
Isodifa 30 mg capsule molli	DK/H/2687/004	045513191	DIFA COOPER S.P.A.	IT
Isodifa 30 mg capsule molli	DK/H/2687/004	045513203	DIFA COOPER S.P.A.	IT
Isodifa 5 mg capsule molli	DK/H/2687/001	045513013	DIFA COOPER S.P.A.	IT
Isodifa 5 mg capsule molli	DK/H/2687/001	045513025	DIFA COOPER S.P.A.	IT
Isodifa 5 mg capsule molli	DK/H/2687/001	045513037	DIFA COOPER S.P.A.	IT
Isodifa 5 mg capsule molli	DK/H/2687/001	045513049	DIFA COOPER S.P.A.	IT
Isodifa 5 mg capsule molli	DK/H/2687/001	045513052	DIFA COOPER S.P.A.	IT
ISORIAC 10 mg, capsule molli	FR/H/0250/002	037551025	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 10 mg, capsule molli	FR/H/0250/002	037551037	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 10 mg, capsule molli	FR/H/0250/002	037551049	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 10 mg, capsule molli	FR/H/0250/002	037551013	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 10 mg, capsule molli	FR/H/0250/002	037551052	PIERRE FABRE ITALIA 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
ISORIAC 20 mg, capsule molli	FR/H/0250/003	037551076	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 20 mg, capsule molli	FR/H/0250/003	037551064	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 20 mg, capsule molli	FR/H/0250/003	037551088	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 20 mg, capsule molli	FR/H/0250/003	037551090	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 20 mg, capsule molli	FR/H/0250/003	037551102	PIERRE FABRE ITALIA S.P.A.	IT
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
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

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	039964109	DIFA COOPER S.P.A.	IT
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	036083057	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083069	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083071	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083083	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083095	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083107	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083119	DIFA COOPER S.P.A.	IT
NOIDAK	NL/H/3739/001	045046012	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/001	045046024	VELIT BIOPHARMA S.R.L	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
NOIDAK	NL/H/3739/001	045046036	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/001	045046048	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/001	045046051	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/001	045046063	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/002	045046075	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/002	045046087	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/002	045046099	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/002	045046101	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/002	045046113	VELIT BIOPHARMA S.R.L	IT
NOIDAK	NL/H/3739/002	045046125	VELIT BIOPHARMA S.R.L	IT
Isotretinoin Sandoz 10 mg minkštosios kapsulės	NL/H/4820/002	LT/1/20/4571/001	SANDOZ PHARMACEUTICALS D.D.	LT
Isotretinoin Sandoz 10 mg minkštosios kapsulės	NL/H/4820/002	LT/1/20/4571/002	SANDOZ PHARMACEUTICALS D.D.	LT
Isotretinoin Sandoz 10 mg minkštosios kapsulės	NL/H/4820/002	LT/1/20/4571/003	SANDOZ PHARMACEUTICALS D.D.	LT
Isotretinoin Sandoz 10 mg minkštosios kapsulės	NL/H/4820/002	LT/1/20/4571/004	SANDOZ PHARMACEUTICALS D.D.	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
Isotretinoin Sandoz 20 mg minkštosios kapsulės	NL/H/4820/003	LT/1/20/4572/001	SANDOZ PHARMACEUTICALS D.D.	LT
Isotretinoin Sandoz 20 mg minkštosios kapsulės	NL/H/4820/003	LT/1/20/4572/002	SANDOZ PHARMACEUTICALS D.D.	LT
Isotretinoin Sandoz 20 mg minkštosios kapsulės	NL/H/4820/003	LT/1/20/4572/003	SANDOZ PHARMACEUTICALS D.D.	LT
Isotretinoin Sandoz 20 mg minkštosios kapsulės	NL/H/4820/003	LT/1/20/4572/004	SANDOZ PHARMACEUTICALS D.D.	LT
Isotretinoin Sandoz 5 mg minkštosios kapsulės	NL/H/4820/001	LT/1/20/4570/001	SANDOZ PHARMACEUTICALS D.D.	LT
Isotretinoin Sandoz 5 mg minkštosios kapsulės	NL/H/4820/001	LT/1/20/4570/002	SANDOZ PHARMACEUTICALS D.D.	LT
Roaccutane 10 mg minkštosios kapsulės	EE/H/0271/001	LT/1/05/0406/003	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštosios kapsulės	EE/H/0271/001	LT/1/05/0406/001	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštosios kapsulės	EE/H/0271/001	LT/1/05/0406/004	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštosios kapsulės	EE/H/0271/001	LT/1/05/0406/002	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštosios kapsulės	EE/H/0271/002	LT/1/05/0406/006	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštosios kapsulės	EE/H/0271/002	LT/1/05/0406/008	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštosios kapsulės	EE/H/0271/002	LT/1/05/0406/007	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštosios kapsulės	EE/H/0271/002	LT/1/05/0406/005	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
CURACNÉ 40 mg, capsule molle	FR/H/0250/004	0472984	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427913	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427927	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427931	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427944	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427958	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0427961	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0427975	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0427989	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0427992	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0428003	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427846	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427863	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427877	PIERRE FABRE MEDICAMENT	LU

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 Gé 5 mg, capsule molle	FR/H/0250/001	0427881	PIERRE FABRE MEDICAMENT	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427894	PIERRE FABRE MEDICAMENT	LU
Isotiorga 20 mg capsules molles	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL SA	LU
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL SA	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Roaccutane 10 mg capsules molles	EE/H/0271/001	2010010651	N.V. ROCHE S.A.	LU
Roaccutane 10 mg Weichkapseln	EE/H/0271/001	2010010651	N.V. ROCHE S.A.	LU
Roaccutane 20 mg capsules molles	EE/H/0271/002	2010040736	N.V. ROCHE S.A.	LU
Roaccutane 20 mg Weichkapseln	EE/H/0271/002	2010040736	N.V. ROCHE S.A.	LU
Isotretinoin Sandoz 10 mg mīkstās kapsulas	NL/H/4820/002	20-0059	SANDOZ PHARMACEUTICALS D.D.	LV
Isotretinoin Sandoz 20 mg mīkstās kapsulas	NL/H/4820/003	20-0060	SANDOZ PHARMACEUTICALS D.D.	LV
Isotretinoin Sandoz 5 mg mīkstās kapsulas	NL/H/4820/001	20-0058	SANDOZ PHARMACEUTICALS D.D.	LV
Roaccutane 10 mg mīkstās kapsulas	EE/H/0271/001	05-0517	ROCHE LATVIJA SIA	LV

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 20 mg mīkstās kapsulas	EE/H/0271/002	05-0518	ROCHE LATVIJA SIA	LV
Isotretinoīne Aurobindo 10 mg, capsules	PT/H/1878/001	RVG 27577	AUROBINDO PHARMA B.V.	NL
Isotretinoīne Aurobindo 20 mg, capsules	PT/H/1878/002	RVG 27578	AUROBINDO PHARMA B.V.	NL
Isotretinoīne Mylan 10 mg, zachte capsules	NL/H/4813/002	RVG 27573	MYLAN PHARMACEUTICALS LIMITED	NL
Isotretinoīne Mylan 20 mg, zachte capsules	NL/H/4813/003	RVG 27574	MYLAN PHARMACEUTICALS LIMITED	NL
Isotretinoīne Sandoz 10 mg, zachte capsules	NL/H/4820/002	RVG 124602	SANDOZ B.V.	NL
Isotretinoīne Sandoz 20 mg, zachte capsules	NL/H/4820/003	RVG 124603	SANDOZ B.V.	NL
Isotretinoīne Sandoz 5 mg, zachte capsules	NL/H/4820/001	RVG 124601	SANDOZ B.V.	NL
Isotretinoīne SUN 10 mg, zachte capsules	NL/H/3739/001	RVG 119052	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Isotretinoīne SUN 20 mg, zachte capsules	NL/H/3739/002	RVG 119053	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Isotracin 10 mg myke kapsler	AT/H/1017/002	19-12788	2CARE4 GENERICS APS	NO
Isotracin 20 mg myke kapsler	AT/H/1017/003	19-12789	2CARE4 GENERICS APS	NO
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

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Isotretinoin Sandoz 10 mg kapsel, myk	NL/H/4820/002	19-12739	SANDOZ A/S	NO
Isotretinoin Sandoz 20 mg kapsel, myk	NL/H/4820/003	19-12740	SANDOZ A/S	NO
Isotretinoin Sandoz 5 mg kapsel, myk	NL/H/4820/001	19-12738	SANDOZ A/S	NO
Aknenormin, 10 mg, kapsułki miękkie	DE/H/1702/001	11427	ALMIRALL HERMAL GMBH	PL
Aknenormin, 20 mg, kapsułki miękkie	DE/H/1702/002	11426	ALMIRALL HERMAL GMBH	PL
Curacne 10 mg kapsułki, miękkie	FR/H/0250/002	11919	PIERRE FABRE MEDICAMENT	PL
Curacne 20 mg kapsułki, miękkie	FR/H/0250/003	11918	PIERRE FABRE MEDICAMENT	PL
Curacne 40 mg kapsułki, miękkie	FR/H/0250/004	14709	PIERRE FABRE MEDICAMENT	PL
Curacne 5 mg kapsułki, miękkie	FR/H/0250/001	11920	PIERRE FABRE MEDICAMENT	PL
Izotek, 10 mg, kapsułki, miękkie	DK/H/0889/001	12350	BAUSCH HEALTH IRELAND LIMITED	PL
Izotek, 20 mg, kapsułki, miękkie	DK/H/0889/002	12349	BAUSCH HEALTH IRELAND LIMITED	PL
Isotiorga 10 mg cápsulas moles	AT/H/1170/001	5834304	LABORATOIRES BAILLEUL SA	PT
Isotiorga 10 mg cápsulas moles	AT/H/1170/001	5834312	LABORATOIRES BAILLEUL SA	PT
Isotiorga 10 mg cápsulas moles	AT/H/1170/001	5834320	LABORATOIRES BAILLEUL SA	PT

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Isotiorga 10 mg cápsulas moles	AT/H/1170/001	5834338	LABORATOIRES BAILLEUL SA	PT
Isotiorga 20 mg cápsulas moles	AT/H/1170/002	5834346	LABORATOIRES BAILLEUL SA	PT
Isotiorga 20 mg cápsulas moles	AT/H/1170/002	5834353	LABORATOIRES BAILLEUL SA	PT
Isotiorga 20 mg cápsulas moles	AT/H/1170/002	5834361	LABORATOIRES BAILLEUL SA	PT
Isotiorga 20 mg cápsulas moles	AT/H/1170/002	5834379	LABORATOIRES BAILLEUL SA	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057584	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057683	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057782	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057881	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057980	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058087	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058186	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058285	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058384	GENERIS FARMACÊUTICA, S.A.	PT

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Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058483	GENERIS FARMACÊUTICA, S.A.	PT
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
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
Isotretinoína Orotrex, 5 mg cápsulas moles	not available	5750518	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Isotretinoína Orotrex, 5 mg cápsulas moles	not available	5750526	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Isotretinoin Bailleul 10 mg capsule moi	AT/H/1170/001	14554/2022/01	LABORATOIRES BAILLEUL SA	RO
Isotretinoin Bailleul 10 mg capsule moi	AT/H/1170/001	14554/2022/02	LABORATOIRES BAILLEUL SA	RO
Isotretinoin Bailleul 10 mg capsule moi	AT/H/1170/001	14554/2022/03	LABORATOIRES BAILLEUL SA	RO
Isotretinoin Bailleul 10 mg capsule moi	AT/H/1170/001	14554/2022/04	LABORATOIRES BAILLEUL SA	RO
Isotretinoin Bailleul 20 mg capsule moi	AT/H/1170/002	14555/2022/01	LABORATOIRES BAILLEUL SA	RO
Isotretinoin Bailleul 20 mg capsule moi	AT/H/1170/002	14555/2022/02	LABORATOIRES BAILLEUL SA	RO

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 Bailleul 20 mg capsule moi	AT/H/1170/002	14555/2022/03	LABORATOIRES BAILLEUL SA	RO
Isotretinoin Bailleul 20 mg capsule moi	AT/H/1170/002	14555/2022/04	LABORATOIRES BAILLEUL SA	RO
Roaccutane 10 mg capsule moi	not available	7661/2015/01	ROCHE ROMANIA SRL	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	14668/2022/01	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	14668/2022/02	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	14668/2022/03	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	14668/2022/04	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	14668/2022/05	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	14668/2022/06	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	14669/2022/01	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	14669/2022/02	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	14669/2022/03	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	14669/2022/04	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	14669/2022/05	TERAPIA S.A.	RO

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 20 mg capsule moi	NL/H/3739/002/DC	14669/2022/06	TERAPIA S.A.	RO
Isotracin 10 mg mjuka kapslar.	AT/H/1017/002	59029	2CARE4 GENERICS APS	SE
Isotracin 20 mg mjuka kapslar.	AT/H/1017/003	59030	2CARE4 GENERICS APS	SE
ISOTRETINOIN ACTAVIS 10 MG KAPSLAR, MJUKA	DK/H/2242/001	48555	ACTAVIS GROUP PTC EHF.	SE
ISOTRETINOIN ACTAVIS 20 MG KAPSLAR, MJUKA	DK/H/2242/002	48556	ACTAVIS GROUP PTC EHF.	SE
Isotretinoin Orifarm 10 mg kapslar, mjuka	DK/H/1060/001	57967	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	57968	ORIFARM GENERICS A/S	SE
Isotretinoin Sandoz 10 mg mjuka kapslar	NL/H/4820/002	58873	SANDOZ A/S	SE
Isotretinoin Sandoz 20 mg mjuka kapslar	NL/H/4820/003	58874	SANDOZ A/S	SE
Isotretinoin Sandoz 5 mg mjuka kapslar	NL/H/4820/001	58872	SANDOZ A/S	SE
Retitren 10 mg mehke kapsule	not available	H/20/02745/001	BELUPO D.O.O.	SI
Retitren 20 mg mehke kapsule	not available	H/20/02745/002	BELUPO D.O.O.	SI
Aknenormin 10 10 mg mäkke kapsuly	DE/H/1702/001	46/0130/05-S	ALMIRALL HERMAL GMBH	SK
Aknenormin 20 20 mg mäkke kapsuly	DE/H/1702/002	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
BELORETIN 10 mg mäkke kapsuly	not available	46/0390/18-S	BELUPO, S.R.O.	SK
BELORETIN 20 mg mäkke kapsuly	not available	46/0391/18-S	BELUPO, S.R.O.	SK
Isotiorga 20 mg mäkke kapsuly	AT/H/1170/002	46/0115/22-S	LABORATOIRES BAILLEUL SA	SK
ISOTRETINOIN ACTAVIS 10 MG MÄKKÉ KAPSULY	DK/H/2242/001	46/0418/13-S	TEVA B.V	SK
ISOTRETINOIN ACTAVIS 20 MG MÄKKÉ KAPSULY	DK/H/2242/002	46/0419/13-S	TEVA B.V	SK
Isotretinoin 10 mg soft capsules	NL/H/3739/001	PL 31750/0099	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	XI
Isotretinoin 10mg Capsules, soft	not available	PL 40739/0041	ENNOGEN HEALTHCARE LIMITED	XI
Isotretinoin 20 mg soft capsules	not available	PL 40739/0001	ENNOGEN HEALTHCARE LIMITED	XI
Isotretinoin 20 mg soft capsules	NL/H/3739/002	PL 31750/0100	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	XI
Isotretinoin 5 mg capsules	UK/H/7020/001	PL 40739/0002	ENNOGEN HEALTHCARE LIMITED	XI
Roaccutane 10 mg soft capsules	not available	PL 00031/0617	ROCHE PRODUCTS LTD	XI
Roaccutane 20 mg soft capsules	EE/H/0271/002	PL 00031/0160	ROCHE PRODUCTS LTD	XI