



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 20221
EMA/46466/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: isotretinoin (oral formulations)

Procedure no.: PSUSA/00010488/202105

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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
Ciscutan 5 mg – Kapseln	not available	1-29997	PELPHARMA HANDELS GMBH	AT
Ciscutan 40 mg – Kapseln	not available	1-27652	PELPHARMA HANDELS GMBH	AT
Isotretinoin GAP 5 mg Weichkapseln	AT/H/1017/001	140409	GAP S.A.	AT
Isotretinoin GAP 10 mg Weichkapseln	AT/H/1017/002	140405	GAP S.A.	AT
Isotretinoin GAP 20 mg Weichkapseln	AT/H/1017001-004DC	140406	GAP S.A.	AT
Isotretinoin GAP 40 mg Weichkapseln	AT/H/1017001-004DC	140407	GAP S.A.	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
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
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	BE270173	EUROGENERICS N.V./S.A.	BE
Isotretinoïne EG 10 mg zachte capsules	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
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	BE266296	EUROGENERICS N.V./S.A.	BE
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	not available	BE266533	LABORATOIRES SMB S.A.	BE

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Hartkapseln				
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 Hartkapseln	not available	BE266542	LABORATOIRES SMB S.A.	BE
Roacutane 10 mg zachte capsules	EE/H/0271/001	BE130611	N.V. ROCHE S.A.	BE
Roacutane 10 mg Weichkapseln	EE/H/0271/001	BE130611	N.V. ROCHE S.A.	BE
Roacutane 20 mg zachte capsules	EE/H/0271/002	BE130627	N.V. ROCHE S.A.	BE
Roacutane 20 mg Weichkapseln	EE/H/0271/002	BE130627	N.V. ROCHE S.A.	BE
Roacutane 20 mg capsules molles	EE/H/0271/002	BE130627	N.V. ROCHE S.A.	BE
Roacutane 10 mg capsules molles	EE/H/0271/001	BE130611	N.V. ROCHE S.A.	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 40 mg, capsules molles	FR/H/0250/004	BE 334047	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg, capsules molles	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE
ISOCURAL 10 mg, capsules molles	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	BE
ISOCURAL 20 mg, zachte capsules	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX	BE
ISOCURAL 40 mg, zachte capsules	FR/H/0250/004	BE334047	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg, zachte	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE

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capsules				
ISOCURAL 10 mg, capsules molles	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	BE
ISOCURAL 10 mg, capsules molles	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	BE
ISOCURAL 10 mg, capsules molles	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	BE
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 10 mg, zachte capsules	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	BE
ISOCURAL 10 mg, zachte capsules	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, capsules molles	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX	BE
ISOCURAL 20 mg, capsules molles	FR/H/0250/003	BE280427	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 20 mg, zachte capsules	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX	BE
ISOCURAL 20 mg, zachte capsules	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX	BE
ISOCURAL 20 mg, zachte capsules	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg,	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE

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capsules molles				
ISOCURAL 5 mg, capsules molles	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg, capsules molles	FR/H/0250/001	BE280402	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
ISOCURAL 5 mg, zachte capsules	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg, zachte capsules	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg, zachte capsules	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE
Роакутан 20 mg капсули, Roacutane 20 mg capsules, soft	not available	20030084	ROCHE BULGARIA EOOD	BG
Rotaxin 10mg soft gelatin capsules	not available	21122	HADJICONSTANTINOUS BROS	CY
Rotaxin 20mg soft gelatin capsules	not available	21123	HADJICONSTANTINOUS BROS	CY
Acnotren 10mg soft gelatin capsules	not available	20320	SAPIENS PHARMACEUTICALS LTD	CY
Acnotren 20mg soft gelatin capsules	not available	20321	SAPIENS PHARMACEUTICALS LTD	CY
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
Aknenormin 20 mg	DE/H/1702/002	46/139/05-C	ALMIRALL HERMAL GMBH	CZ

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měkké tobolky				
Aknenormin 10 mg měkké tobolky	DE/H/1702/001	46/138/05-C	ALMIRALL HERMAL GMBH	CZ
Isotretinoin Belupo 20 mg měkké tobolky	not available	46/666/15-C	BELUPO, S.R.O.	CZ
Isotretinoin Belupo 10 mg měkké tobolky	not available	46/665/15-C	BELUPO, S.R.O.	CZ
CURACNÉ 10 mg měkké tobolky	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg měkké tobolky	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg měkké tobolky	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg měkké tobolky	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkké tobolky	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkké tobolky	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkké tobolky	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkké tobolky	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg měkké tobolky	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkké tobolky	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 40 mg měkké tobolky	FR/H/0250/004	46/095/08-C	PIERRE FABRE DERMATOLOGIE	CZ
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
Isotret-HEXAL 20 mg	DK/H/0300/002	54100.01.00	HEXAL AG	DE

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Kapseln, Weichkapseln				
Isotretinoin KARLING 10 mg, Weichkapseln	not available	48903.00.00	KARLING PHARMA GMBH	DE
Isotretinoin KARLING 20 mg, Weichkapseln	not available	48903.01.00	KARLING PHARMA GMBH	DE
Aknenormin 20 mg Weichkapseln	DE/H/1702/002	55003.01.00	ALMIRALL HERMAL GMBH	DE
Aknenormin 10 mg Weichkapseln	DE/H/1702/001	55003.00.00	ALMIRALL HERMAL GMBH	DE
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
Isotret-HEXAL 10 mg Kapseln	DK/H/0300/001	54100.00.00	HEXAL AG	DE
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
Pharmiso, bløde kapsler	DK/H/0300/002	31478	HEXAL AG	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/001	51479	ACTAVIS GROUP PTC EHF.	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/002	51480	ACTAVIS GROUP PTC EHF.	DK
Isotretinoin Sandoz	NL/H/4820/001	62364	SANDOZ A/S	DK
Isotretinoin Sandoz	NL/H/4820/002	62365	SANDOZ A/S	DK
Isotretinoin Sandoz	NL/H/4820/003	62366	SANDOZ A/S	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
Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/001	34484	ORIFARM GENERICS A/S	DK

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Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/002	34485	ORIFARM GENERICS A/S	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
Accutin, kapsler, bløde	not available	31531	SANDOZ A/S	DK
Accutin, kapsler, bløde	not available	31532	SANDOZ A/S	DK
Isotretinoin "Difa Cooper", bløde kapsler	DK/H/1749/001	37463	DIFA COOPER S.P.A.	DK
Isotretinoin "Difa", bløde kapsler	DK/H/2687/001	58419	DIFA COOPER S.P.A.	DK
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
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
Isotretinoin "Difa Cooper", bløde kapsler	DK/H/1749/001	37463	DIFA COOPER S.P.A.	DK
Isotretinoin "Difa", bløde kapsler	DK/H/2687/001	58419	DIFA COOPER S.P.A.	DK
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 "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

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Pharmiso, bløde kapsler	DK/H/0300/001	31477	HEXAL AG	DK
Isotretinoin Sandoz 5 mg pehmekapslid	NL/H/4820/001	1006020	SANDOZ PHARMACEUTICALS D.D.	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
Roaccutane 20 mg, pehmekapslid	EE/H/0271/002	404002	ROCHE EESTI OÜ	EE
Roaccutane 10 mg, pehmekapslid	EE/H/0271/001	052294	ROCHE EESTI OÜ	EE
Dercutane 20 mg cápsulas blandas	not available	65.334	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	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
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
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
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
Dercutane 40 mg cápsulas blandas	not available	67.878	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Dercutane 5 mg cápsulas	not available	69.742	INDUSTRIAL FARMACEUTICA	ES

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blandas			CANTABRIA, S.A.	
Dercutane 30 mg cápsulas blandas	not available	78.326	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Dercutane 10 mg cápsulas blandas	not available	65.333	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Acnisdin 40 mg cápsulas blandas	AT/H/1017/004/DC	85748	ISDIN, S.A.	ES
Acnisdin 20 mg cápsulas blandas EFG	AT/H/1017/003/DC	85585	ISDIN, S.A.	ES
Acnisdin 10 mg cápsulas blandas EFG	AT/H/1017/002/DC	85584	ISDIN, 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 40 mg cápsulas blandas	IT/H/0739/04/DC	76.045	ISDIN, S.A.	ES
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
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
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
ISOACNÉ 5 mg cápsulas	FR/H/0250/001	67.464	PIERRE FABRE IBERICA,	ES

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blandas			S.A.	
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
Isotretinoin Orion 20 mg pehmeät kapselit	DK/H/0889/002	21907	PHARMATHEN S.A.	FI
Isotretinoin Actavis 10 mg mjuk kapsel	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
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
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotracin 10 mg pehmeät kapselit.	AT/H/1017/002	36975	2CARE4 GENERICS APS	FI
Isotracin 10 mg mjuka kapslar.	AT/H/1017/002	36975	2CARE4 GENERICS APS	FI
Isotracin 20 mg pehmeät kapselit.	AT/H/1017/003	36976	2CARE4 GENERICS APS	FI
Isotracin 20 mg mjuka kapslar.	AT/H/1017/003	36976	2CARE4 GENERICS APS	FI
Isotretinoin SanoSwiss 20 mg kapseli, pehmeä	FI/H/0993/002	17152	UAB SANOSWISS	FI
ISOTRETINOINE ACNETRAIT 40 mg, capsule molle	not available	NL 36266	ARROW GENERIQUES	FR
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

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CONTRACNE 10 mg, capsule molle	not available	34009 358 122 7 8	LABORATOIRES BAILLEUL SA	FR
ISOTRETINOINE ACNETRAIT 5 mg, capsule molle	not available	NL 36265	ARROW GENERIQUES	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
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
CONTRACNE 40 mg, capsule molle	not available	34009 367 884 3 5	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
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,	not available	34009 358 107 8 6	LABORATOIRES	FR

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capsule molle			EXPANSCIENCE	
PROCUA 10 mg, capsule molle	not available	34009 357 838 9 9	LABORATOIRES EXPANSCIENCE	FR
PROCUA 10 mg, capsule molle	not available	34009 358 108 4 7	LABORATOIRES EXPANSCIENCE	FR
PROCUA 10 mg, capsule molle	not available	34009 358 109 0 8	LABORATOIRES EXPANSCIENCE	FR
PROCUA 10 mg, capsule molle	not available	34009 357 839 5 0	LABORATOIRES EXPANSCIENCE	FR
PROCUA 20 mg, capsule molle	not available	34009 358 104 9 6	LABORATOIRES EXPANSCIENCE	FR
PROCUA 20 mg, capsule molle	not available	34009 357 836 6 0	LABORATOIRES EXPANSCIENCE	FR
PROCUA 20 mg, capsule molle	not available	34009 358 105 5 7	LABORATOIRES EXPANSCIENCE	FR
PROCUA 20 mg, capsule molle	not available	34009 358 106 1 8	LABORATOIRES EXPANSCIENCE	FR
PROCUA 20 mg, capsule molle	not available	34009 357 837 2 1	LABORATOIRES EXPANSCIENCE	FR
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
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 129 1 9	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 115 0 9	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 40 mg, capsule molle	FR/H/0250/004	34009 367 603 4 9	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 123 3 9	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 10 mg,	FR/H/0250/002	34009 358 131 6 9	PIERRE FABRE	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
capsule molle			DERMATOLOGIE	
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 134 5 9	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 132 2 0	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 133 9 8	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 135 1 0	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 136 8 8	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 157 5 0	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 158 1 1	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 125 6 8	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 126 2 9	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 127 9 7	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 128 5 8	PIERRE FABRE DERMATOLOGIE	FR
PROCUTA 40 mg, capsule molle	not available	34009 367 880 8 4	LABORATOIRES EXPANSCIENCE	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 116 7 7	LABORATOIRES SA BAILLEUL	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 117 3 8	LABORATOIRES SA BAILLEUL	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 119 6 7	LABORATOIRES SA BAILLEUL	FR
CONTRACNE 10 mg, capsule molle	not available	34009 358 120 4 9	LABORATOIRES SA BAILLEUL	FR
CONTRACNE 10 mg, capsule molle	not available	34009 358 121 0 0	LABORATOIRES SA BAILLEUL	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
capsule molle			SA	
CONTRACNE 10 mg, capsule molle	not available	34009 358 122 7 8	LABORATOIRES BAILLEUL SA	FR
A-CNOTREN 10 mg καψάκια, μαλακά	DK/H/0889/001	45/16-01-2012	PHARMATHEN INVESTMENTS GROUP LIMITED	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
ISOTROIN® 10 mg καψάκιο, μαλακό	not available	76447/10-11-11	IASIS PHARMA	GR
ISOTROIN® 20 mg καψάκιο, μαλακό	not available	76449/10-11-11	IASIS PHARMA	GR
ISOTROIN® 40 mg καψάκιο, μαλακό	not available	78135/10-11-11	IASIS PHARMA	GR
Isotroin 30 mg καψάκιο, μαλακό	not available	104547/02-11-20	IASIS PHARMA	GR
A-CNOTREN 20 mg καψάκια, μαλακά	not available	45047/10/18-04-2012	PHARMATHEN INVESTMENTS GROUP LIMITED	GR
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
Roaccutane 10 mg meke kapsule	not available	HR-H-462694255	ROCHE D.O.O.	HR
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
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

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
kapszula				
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
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-22560/06	ACTAVIS GROUP PTC EHF.	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
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

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kapszula				
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
Isotretinoin Zentiva 10 mg lágy kapszula	not available	OGYI-T-20238/01	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 10 mg lágy kapszula	not available	OGYI-T-20238/02	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 10 mg lágy kapszula	not available	OGYI-T-20238/03	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 10 mg lágy kapszula	not available	OGYI-T-20238/04	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 10 mg lágy kapszula	not available	OGYI-T-20238/05	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 20 mg lágy kapszula	not available	OGYI-T-20238/10	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 20 mg lágy kapszula	not available	OGYI-T-20238/06	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 20 mg lágy kapszula	not available	OGYI-T-20238/07	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 20 mg lágy kapszula	not available	OGYI-T-20238/08	ZENTIVA, K.S.	HU
Isotretinoin Zentiva 20 mg lágy kapszula	not available	OGYI-T-20238/09	ZENTIVA, K.S.	HU
Isotretinoin 5 mg soft capsules	NL/H/4820/001	PA0711/312/001	ROWEX LTD	IE
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

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capsules				
Isotretinoin GAP 10 mg capsule, soft	AT/H/1017/001-004/DC	PA22735/002/001	GAP S.A.	IE
Isotretinoin GAP 20 mg capsule, soft	AT/H/1017/001-004/DC	PA22735/002/002	GAP S.A.	IE
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
Isotretinoin ratiopharm 20 mg mjúk hylki	IS/H/0290/001	IS/1/14/036/01	RATIOPHARM GMBH	IS
Decutan 20 mg hylki, mjúk	DK/H/0368/002	IS/1/02/035/02	ACTAVIS GROUP PTC EHF.	IS
Decutan 10 mg hylki, mjúk	DK/H/0368/001	IS/1/02/035/01	ACTAVIS GROUP PTC EHF.	IS
Isotretinoina SUN 20 mg capsule molli	NL/H/3739/002	045046075	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 20 mg capsule molli	NL/H/3739/002	045046087	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 20 mg capsule molli	NL/H/3739/002	045046113	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 20 mg capsule molli	NL/H/3739/002	045046101	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 20 mg capsule molli	NL/H/3739/002	045046125	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 20 mg capsule molli	NL/H/3739/002	045046099	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046012	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046024	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046063	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046036	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT

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capsule molli			INDUSTRIES EUROPE B.V.	
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046051	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Isotretinoina SUN 10 mg capsule molli	NL/H/3739/001	045046048	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
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
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
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
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	DK/H/1749/001	039964034	DIFA COOPER S.P.A.	IT

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capsule molli				
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
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964109	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
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	DK/H/2687/002	045513102	DIFA COOPER S.P.A.	IT

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molli				
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
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
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083119	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/0298/001-002	036083057/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper	DK/H/0298/002	036083069/M	DIFA COOPER S.P.A.	IT

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20 mg capsule molli				
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
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
Isotretinoina difa 40 mg capsule molli	DK/H/1749/001	039964109	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	DK/H/2687/001	045513037	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
molli				
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
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
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	DK/H/2687/004	045513203	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
molli				
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083119	DIFA COOPER 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 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
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
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	DK/H/0298/001	036083044	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
10 mg capsule molli				
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001-002	036083057/M	DIFA COOPER S.P.A.	IT
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
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083119	DIFA COOPER S.P.A.	IT
ISORIAC 10 mg, capsule molli	FR/H/0250/002	037551025	PIERRE FABRE ITALIA S.P.A.	IT
ISORIAC 20 mg, capsule molli	FR/H/0250/003	037551076	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
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

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
moli				
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
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
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
Roaccutane 10 mg minkštos kapsulės	EE/H/0271/001	LT/1/05/0406/003	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštos kapsulės	EE/H/0271/001	LT/1/05/0406/001	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštos kapsulės	EE/H/0271/002	LT/1/05/0406/006	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštos kapsulės	EE/H/0271/001	LT/1/05/0406/004	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštos kapsulės	EE/H/0271/002	LT/1/05/0406/008	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštos kapsulės	EE/H/0271/002	LT/1/05/0406/007	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg	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
minkštos kapsulės				
Roaccutane 10 mg minkštos kapsulės	EE/H/0271/001	LT/1/05/0406/002	UAB "ROCHE LIETUVA"	LT
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Roaccutane 10 mg Weichkapseln	EE/H/0271/001	2010010651	N.V. ROCHE S.A.	LU
Roaccutane 20 mg Weichkapseln	EE/H/0271/002	2010040736	N.V. ROCHE S.A.	LU
Roaccutane 10 mg capsules molles	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
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427913	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0427961	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ 40 mg, capsule molle	FR/H/0250/004	0427984	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427846	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427927	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427931	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427944	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 10 mg, capsule molle	FR/H/0250/002	0427958	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0427975	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0427989	PIERRE FABRE	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
capsule molle			DERMATOLOGIE	
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0427992	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 20 mg, capsule molle	FR/H/0250/003	0428003	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427863	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427877	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427881	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ Gé 5 mg, capsule molle	FR/H/0250/001	0427894	PIERRE FABRE DERMATOLOGIE	LU
Isotretinoïn Sandoz 5 mg mīkstās kapsulas	NL/H/4820/001	20-0058	SANDOZ PHARMACEUTICALS D.D.	LV
Isotretinoïn Sandoz 10 mg mīkstās kapsulas	NL/H/4820/002	20-0059	SANDOZ PHARMACEUTICALS D.D.	LV
Isotretinoïn Sandoz 20 mg mīkstās kapsulas	NL/H/4820/003	20-0060	SANDOZ PHARMACEUTICALS D.D.	LV
Roaccutane 10 mg mīkstās kapsulas	EE/H/0271/001	05-0517	ROCHE LATVIJA SIA	LV
Roaccutane 20 mg mīkstās kapsulas	EE/H/0271/002	05-0518	ROCHE LATVIJA SIA	LV
Isotretinoīne SUN 20 mg, zachte capsules	NL/H/3739/002	RVG 119053	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Isotretinoīne SUN 10 mg, zachte capsules	NL/H/3739/001	RVG 119052	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Isotretinoīne Sandoz 5 mg, zachte capsules	NL/H/4820/001	RVG 124601	SANDOZ B.V.	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 Aurobindo	PT/H/1878/001	RVG 27577	AUROBINDO PHARMA 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
10 mg, capsules				
Isotretinoïne Aurobindo 20 mg, capsules	PT/H/1878/002	RVG 27578	AUROBINDO PHARMA B.V.	NL
Isotretinoïne Mylan 10 mg, zachte capsules	NL/H/4813/002	RVG 27573	MYLAN B.V.	NL
Isotretinoïne Mylan 20 mg, zachte capsules	NL/H/4813/003	RVG 27574	MYLAN B.V.	NL
Isotretinoin Sandoz 5 mg kapsel, myk	NL/H/4820/001	19-12738	SANDOZ A/S	NO
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 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
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
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
Axotret, 10 mg, kapsułki miękkie	not available	11318	ARISTO PHARMA SP. Z O.O.	PL
Axotret, 20 mg, kapsułki miękkie	not available	11319	ARISTO PHARMA SP. Z O.O.	PL
Aknenormin, 20 mg, kapsułki miękkie	DE/H/1702/002	11426	ALMIRALL HERMAL GMBH	PL
Aknenormin, 10 mg, kapsułki miękkie	DE/H/1702/001	11427	ALMIRALL HERMAL GMBH	PL
Axotret, 10 mg, kapsułki	not available	11318	ARISTO PHARMA SP. Z O.O.	PL

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
miękkie				
Axotret, 20 mg, kapsułki miękkie	not available	11319	ARISTO PHARMA SP. Z O.O.	PL
Curacne 10 mg kapsułki, miękkie	FR/H/0250/002	11919	PIERRE FABRE DERMATOLOGIE	PL
Curacne 20 mg kapsułki, miękkie	FR/H/0250/003	11918	PIERRE FABRE DERMATOLOGIE	PL
Curacne 40 mg kapsułki, miękkie	FR/H/0250/004	14709	PIERRE FABRE DERMATOLOGIE	PL
Curacne 5 mg kapsułki, miękkie	FR/H/0250/001	11920	PIERRE FABRE DERMATOLOGIE	PL
Curacne 10 mg kapsułki, miękkie	FR/H/0250/002	11919	PIERRE FABRE DERMATOLOGIE	PL
Curacne 20 mg kapsułki, miękkie	FR/H/0250/003	11918	PIERRE FABRE DERMATOLOGIE	PL
Axotret, 10 mg, kapsułki miękkie	not available	11318	ARISTO PHARMA SP. Z O.O.	PL
Axotret, 20 mg, kapsułki miękkie	not available	11319	ARISTO PHARMA SP. Z O.O.	PL
Isotretinoína Mer 20 mg Cápsulas moles	not available	5678198	AXONE, LDA.	PT
Isotretinoína Mer 20 mg Cápsulas moles	not available	5678297	AXONE, LDA.	PT
Isotretinoína Mer 20 mg Cápsulas moles	not available	5678396	AXONE, LDA.	PT
Isotretinoína Mer 10 mg Cápsulas moles	not available	5677893	AXONE, LDA.	PT
Isotretinoína Mer 10 mg Cápsulas moles	not available	5677992	AXONE, LDA.	PT
Isotretinoína Mer 10 mg Cápsulas moles	not available	5678099	AXONE, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057584	GENERIS FARMACÉUTICA, S.A.	PT
Isotretinoína Aurovitas	PT/H/1878/001	4057683	GENERIS FARMACÉUTICA,	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
10 mg Cápsulas moles			S.A.	
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
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058483	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Isdin 10 mg cápsulas moles	not available	5790241	ISDIN LDA	PT
Isotretinoína Isdin 10 mg cápsulas moles	not available	5790233	ISDIN LDA	PT
Isotretinoína Isdin 20 mg cápsulas moles	not available	5790258	ISDIN LDA	PT
Isotretinoína Isdin 20 mg cápsulas moles	not available	5790266	ISDIN LDA	PT
Isotretinoína Mer 20 mg Cápsulas moles	not available	5678198	AXONE, LDA.	PT
Isotretinoína Mer 20 mg Cápsulas moles	not available	5678297	AXONE, LDA.	PT
Isotretinoína Mer 20 mg Cápsulas moles	not available	5678396	AXONE, LDA.	PT
Isotretinoína Mer 10 mg Cápsulas moles	not available	5677893	AXONE, LDA.	PT
Isotretinoína Mer 10 mg	not available	5677992	AXONE, 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
Cápsulas moles				
Isotretinoína Mer 10 mg Cápsulas moles	not available	5678099	AXONE, LDA.	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
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
Sotret 10 mg capsule moi	NL/H/3739/001	10194/2017/01	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001	10194/2017/02	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001	10194/2017/03	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001	10194/2017/04	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001	10194/2017/05	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 10 mg capsule moi	NL/H/3739/001	10194/2017/06	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002	10195/2017/01	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002	10195/2017/02	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002	10195/2017/03	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002	10195/2017/04	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002	10195/2017/05	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002	10195/2017/06	TERAPIA S.A.	RO
Roaccutane 10 mg capsule moi	not available	7661/2015/01	ROCHE ROMANIA SRL	RO
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 Sandoz 5 mg mjuka kapslar	NL/H/4820/001	58872	SANDOZ 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 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
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

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
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
Roaccutane 10 mg mehke kapsule	EE/H/0271/001	H/96/01368/002	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg mehke kapsule	EE/H/0271/001	H/96/01368/003	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	EE/H/0271/002	H/96/01368/007	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	EE/H/0271/002	H/96/01368/008	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg mehke kapsule	EE/H/0271/001	H/96/01368/004	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	EE/H/0271/002	H/96/01368/006	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg mehke kapsule	EE/H/0271/001	H/96/01368/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	EE/H/0271/002	H/96/01368/005	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
ISOTRETINOIN ACTAVIS 10 MG MÄKKÉ KAPSULY	DK/H/2242/001	46/0418/13-S	ACTAVIS GROUP PTC EHF.	SK
ISOTRETINOIN ACTAVIS 20 MG MÄKKÉ KAPSULY	DK/H/2242/002	46/0419/13-S	ACTAVIS GROUP PTC EHF.	SK
Aknenormin 20 20 mg mäkké kapsuly	DE/H/1702/002	46/0129/05-S	ALMIRALL HERMAL GMBH	SK
Aknenormin 10 10 mg mäkké kapsuly	DE/H/1702/001	46/0130/05-S	ALMIRALL HERMAL GMBH	SK
BELORETIN® 20 mg mäkké kapsuly	not available	46/0391/18-S	BELUPO, S.R.O.	SK
BELORETIN® 10 mg mäkké kapsuly	not available	46/0390/18-S	BELUPO, S.R.O.	SK
CURACNÉ 40 mg mäkké kapsuly	FR/H/0250/004	46/0119/08-S	PIERRE FABRE DERMATOLOGIE	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
Isotretinoin 5 mg capsules	UK/H/7020/001/DC	PL 40739/0002	ENNOGEN HEALTHCARE LIMITED	XI
Isotretinoin 20mg soft capsules	not available	PL 40739/0001	ENNOGEN HEALTHCARE LIMITED	XI
Rizuderm 5mg Capsules	not available	PL 16853/0132	ALLIANCE PHARMACEUTICALS LTD	XI
Isotretinoin 20mg Capsules	not available	PL 16853/0133	ALLIANCE PHARMACEUTICALS LTD	XI
Isotretinoin 5mg Capsules	not available	PL 16853/0132	ALLIANCE PHARMACEUTICALS LTD	XI
Rizuderm 20mg Capsules	not available	PL 16853/0133	ALLIANCE PHARMACEUTICALS LTD	XI
Isotretinoin 5 mg capsules	UK/H/7020/001/DC	PL 40739/0002	ENNOGEN HEALTHCARE LIMITED	XI
Isotretinoin 20mg soft capsules	not available	PL 40739/0001	ENNOGEN HEALTHCARE LIMITED	XI
Isotretinoin 5 mg capsules	UK/H/7020/001/DC	PL 40739/0002	ENNOGEN HEALTHCARE LIMITED	XI
Isotretinoin 20mg soft capsules	not available	PL 40739/0001	ENNOGEN HEALTHCARE LIMITED	XI
Isotretinoin 10 mg Soft Capsules	IT/H/0739/002	PL 04569/1344	GENERICS [UK] LIMITED	XI
Isotretinoin 20 mg Soft Capsules	IT/H/0739/003	PL 04569/1345	GENERICS [UK] LIMITED	XI
Isotretinoin 40 mg Soft Capsules	IT/H/0739/004	PL 04569/1346	GENERICS [UK] LIMITED	XI
Isotretinoin 5 mg Soft Capsules	IT/H/0739/001	PL 04569/1343	GENERICS [UK] LIMITED	XI
Roaccutane 10 mg soft capsules	EE/H/0271/001	PL 00031/0617	ROCHE PRODUCTS LTD	XI
Roaccutane 20 mg soft capsules	EE/H/0271/002	PL 00031/0160	ROCHE PRODUCTS LTD	XI