



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 December 2025
EMADOC-1700519818-2824312
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): isotretinoin (oral formulations)

EURD list No. PSUSA/00010488/202505



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 S.A.	AT
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	141358	LABORATOIRES BAILLEUL S.A.	AT
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	141358	LABORATOIRES BAILLEUL S.A.	AT
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	141358	LABORATOIRES BAILLEUL S.A.	AT
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	141360	LABORATOIRES BAILLEUL S.A.	AT
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	141360	LABORATOIRES BAILLEUL S.A.	AT
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	141360	LABORATOIRES BAILLEUL S.A.	AT
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	141360	LABORATOIRES BAILLEUL 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
Isotiorga 40 mg Weichkapseln	AT/H/1170/003	141362	LABORATOIRES BAILLEUL S.A.	AT
Isotretinoin GAP 10 mg Weichkapseln	AT/H/1017/002	140405	GAP S.A.	AT
Isotretinoin GAP 10 mg Weichkapseln.	AT/H/1017/002	140405	GAP S.A.	AT
Isotretinoin GAP 10 mg Weichkapseln.	AT/H/1017/002	140405	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 20 mg Weichkapseln.	AT/H/1017/003	140406	GAP S.A.	AT
Isotretinoin GAP 20 mg Weichkapseln.	AT/H/1017/003	140406	GAP S.A.	AT
Isotretinoin GAP 20 mg Weichkapseln.	AT/H/1017/003	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
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
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

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
Isotiorga 10 mg capsules molles	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg capsules molles	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg capsules molles	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg capsules molles	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg zachte capsules	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg zachte capsules	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg zachte capsules	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 10 mg zachte capsules	AT/H/1170/001	BE596071	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg capsules molles	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg capsules molles	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg capsules molles	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg capsules molles	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL 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
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg zachte capsules	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg zachte capsules	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg zachte capsules	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	BE
Isotiorga 20 mg zachte capsules	AT/H/1170/002	BE596080	LABORATOIRES BAILLEUL S.A.	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
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	CHEPLAPHARM REGISTRATION GMBH	BE
Roaccutane 20 mg Capsules molles	EE/H/0271/002	BE130627	CHEPLAPHARM REGISTRATION GMBH	BE
Роакутан 20 мг капсули, меки	not available	20030084	ROCHE BULGARIA EOOD	BG
Роакутан 20 мг капсули, меки	not available	20030084	ROCHE BULGARIA EOOD	BG

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
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
Aknenormin 10 mg měkké tobolky	DE/H/1702/001	46/138/05-C	ALMIRALL HERMAL GMBH	CZ
Aknenormin 20 mg měkké tobolky	DE/H/1702/002	46/139/05-C	ALMIRALL HERMAL GMBH	CZ
Asotiorga 20 mg mekké tobolky	AT/H/1170/002	46/491/20-C	LABORATOIRES BAILLEUL S.A.	CZ
Asotiorga 20 mg mekké tobolky	AT/H/1170/002	46/491/20-C	LABORATOIRES BAILLEUL S.A.	CZ
Asotiorga 20 mg mekké tobolky	AT/H/1170/002	46/491/20-C	LABORATOIRES BAILLEUL S.A.	CZ
Asotiorga 20 mg měkké tobolky	AT/H/1170/002	46/491/20-C	LABORATOIRES BAILLEUL S.A.	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 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

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
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 S.A.	DE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	7003560.00.00	LABORATOIRES BAILLEUL S.A.	DE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	7003560.00.00	LABORATOIRES BAILLEUL S.A.	DE
Isotiorga 10 mg Weichkapseln	AT/H/1170/001	7003560.00.00	LABORATOIRES BAILLEUL S.A.	DE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	7003561.00.00	LABORATOIRES BAILLEUL S.A.	DE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	7003561.00.00	LABORATOIRES BAILLEUL S.A.	DE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	7003561.00.00	LABORATOIRES BAILLEUL S.A.	DE
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	7003561.00.00	LABORATOIRES BAILLEUL S.A.	DE
Isotret-HEXAL 10 mg Kapseln, Weichkapseln	DK/H/0300/001	54100.00.00	HEXAL AG	DE
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-ratiopharm® 10 mg Weichkapseln	DK/H/0298/001	54096.00.00	RATIOPHARM GMBH	DE
Isotretinoin-ratiopharm® 10 mg Weichkapseln	DK/H/0298/001	54096.00.00	RATIOPHARM GMBH	DE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Isotretinoin-ratiopharm® 10 mg Weichkapseln	DK/H/0298/001	54096.00.00	RATIOPHARM GMBH	DE
Isotretinoin-ratiopharm® 10 mg Weichkapseln	DK/H/0298/001	54096.00.00	RATIOPHARM GMBH	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
Isotretinoin-ratiopharm® 20 mg Weichkapseln	DK/H/0298/002	54096.01.00	RATIOPHARM GMBH	DE
Isotretinoin-ratiopharm® 20 mg Weichkapseln	DK/H/0298/002	54096.01.00	RATIOPHARM GMBH	DE
Isotretinoin-ratiopharm® 20 mg Weichkapseln	DK/H/0298/002	54096.01.00	RATIOPHARM GMBH	DE
Isotretinoin-ratiopharm® 20 mg Weichkapseln	DK/H/0298/002	54096.01.00	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/2242/001	51479	TEVA B.V	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
ACNENOR, BLØDE KAPSLER	DK/H/2242/001	51479	TEVA B.V	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/001	51479	TEVA B.V	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/001	51479	TEVA B.V	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/002	51480	TEVA B.V	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/002	51480	TEVA B.V	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/002	51480	TEVA B.V	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/002	51480	TEVA B.V	DK
ACNENOR, BLØDE KAPSLER	DK/H/2242/002	51480	TEVA B.V	DK
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/0368/002	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
Isotretinoin "Difa", bløde kapsler	DK/H/2687/002	58420	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/2687/003	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/1060/001	34484	ORIFARM GENERICS A/S	DK
Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/001	34484	ORIFARM GENERICS A/S	DK
Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/001	34484	ORIFARM GENERICS A/S	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 "Orifarm", bløde kapsler	DK/H/1060/002	34485	ORIFARM GENERICS A/S	DK
Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/002	34485	ORIFARM GENERICS A/S	DK
Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/002	34485	ORIFARM GENERICS A/S	DK
Isotretinoin "Orifarm", bløde kapsler	DK/H/1060/002	34485	ORIFARM GENERICS A/S	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/0889/001	34932	PHARMATHEN S.A.	DK
Isotretinoin "Orion", bløde kapsler	DK/H/0889/002	34933	PHARMATHEN S.A.	DK
Isotretinoin "Sandoz", bløde kapsler	NL/H/4820/001	62364	SANDOZ A/S	DK

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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/0298/001	31473	TEVA B.V	DK
Isotretinoin "Teva", bløde kapsler	DK/H/0298/002	31474	TEVA B.V	DK
Isotretinoin "Teva", bløde kapsler	DK/H/0298/002	31474	TEVA B.V	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 "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 S.A.	EE
Isotiorga, 20 mg pehmekapslid	AT/H/1170/002	1058322	LABORATOIRES BAILLEUL S.A.	EE
Isotiorga, 20 mg pehmekapslid	AT/H/1170/002	1058322	LABORATOIRES BAILLEUL S.A.	EE
Isotiorga, 20 mg pehmekapslid	AT/H/1170/002	1058322	LABORATOIRES BAILLEUL S.A.	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

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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 EFG	not available	82566	LABORATORIOS VIÑAS, S.A.	ES
Acnemin 20 mg cápsulas blandas EFG	not available	82567	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
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	ES

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			CENTRUM, S.A.	
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 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 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 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 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

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Flexresan 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
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, 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
			CENTRUM, S.A.	
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACÉUTICAS CENTRUM, S.A.	ES
Flexresan 20 mg cápsulas blandas	not available	66.159	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
Isotiorga 20 mg cápsulas blandas EFG	AT/H/1170/002	86648	LABORATOIRES BAILLEUL S.A.	ES
Isotiorga 40 mg cápsulas blandas	AT/H/1170/003	86649	LABORATOIRES BAILLEUL S.A.	ES
MAYESTA 10 mg cápsulas blandas	not available	69.571	ALFASIGMA ESPAÑA, S.L.	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
MAYESTA 20 mg cápsulas blandas	not available	69.572	ALFASIGMA ESPAÑA, S.L.	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
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapseli, pehmeä	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	24197	ORIFARM GENERICS A/S	FI
Isotretinoin Orion 20 mg pehmeät kapselit	DK/H/0889/002	21907	PHARMATHEN S.A.	FI
CONTRACNE 10 mg, capsule molle	not available	34009 358 120 4 9	LABORATOIRES BAILLEUL S.A.	FR
CONTRACNE 10 mg, capsule molle	not available	34009 358 121 0 0	LABORATOIRES BAILLEUL S.A.	FR
CONTRACNE 10 mg, capsule molle	not available	34009 358 122 7 8	LABORATOIRES BAILLEUL S.A.	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 116 7 7	LABORATOIRES BAILLEUL S.A.	FR

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
CONTRACNE 20 mg, capsule molle	not available	34009 358 117 3 8	LABORATOIRES BAILLEUL S.A.	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 119 6 7	LABORATOIRES BAILLEUL S.A.	FR
CONTRACNE 40 mg, capsule molle	not available	34009 367 884 3 5	LABORATOIRES BAILLEUL S.A.	FR
CONTRACNE 5 mg, capsule molle	not available	34009 382 601 9 9	LABORATOIRES BAILLEUL S.A.	FR
CONTRACNE 5 mg, capsule molle	not available	34009 382 602 5 0	LABORATOIRES BAILLEUL S.A.	FR
ISOTRETINOINE ACNETRAIT 10 mg, capsule molle	not available	62121489	ARROW GENERIQUES	FR
ISOTRETINOINE ACNETRAIT 20 mg, capsule molle	not available	60265569	ARROW GENERIQUES	FR
ISOTRETINOINE ACNETRAIT 40 mg, capsule molle	not available	62872308	ARROW GENERIQUES	FR
ISOTRETINOINE ACNETRAIT 5 mg, capsule molle	not available	64168039	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

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
PROCUTA 20 mg, capsule molle	not available	34009 358 104 9 6	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 357 836 6 0	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 105 5 7	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 106 1 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 357 837 2 1	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 40 mg, capsule molle	not available	34009 367 880 8 4	LABORATOIRES EXPANSCIENCE	FR
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 S.A.	GR
Isotretinoin/Bailleul 20 mg καψάκια,	AT/H/1170/002	51520/25-05-2022	LABORATOIRES BAILLEUL S.A.	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
μαλακά				
Isotretinoin/Bailleul 20 mg καψάκια, μαλακά	AT/H/1170/002	51520/25-05-2022	LABORATOIRES BAILLEUL S.A.	GR
Isotretinoin/Bailleul 20 mg καψάκια, μαλακά	AT/H/1170/002	51520/25-05-2022	LABORATOIRES BAILLEUL S.A.	GR
Isotretinoin/Bailleul 40 mg καψάκια, μαλακά	AT/H/1170/003	51521/25-05-2022	LABORATOIRES BAILLEUL S.A.	GR
ISOTROIN 20 mg καψάκιο, μαλακό	not available	76449/10-11-11	IASIS PHARMA	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
ISOTROIN® 10 mg καψάκιο, μαλακό	not available	76447/10-11-11	IASIS PHARMA	GR
ISOTROIN® 40 mg καψάκιο, μαλακό	not available	78135/10-11-11	IASIS PHARMA	GR
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	2426102	TARGET PHARMA SINGLE MEMBER PRIVATE LTD	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
Tretin 20 mg μαλακά καψάκια	not available	2426103	TARGET PHARMA SINGLE MEMBER PRIVATE LTD	GR
Roaccutane 10 mg meke kapsule	not available	HR-H-462694255	CHEPLAPHARM REGISTRATION GMBH	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
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 S.A.	HU
Isotiorga 20 mg lágy kapszula	AT/H/1170/002	OGYI-T-24042/02	LABORATOIRES BAILLEUL S.A.	HU

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Isotiorga 20 mg lágy kapszula	AT/H/1170/002	OGYI-T-24042/03	LABORATOIRES BAILLEUL S.A.	HU
Isotiorga 20 mg lágy kapszula	AT/H/1170/002	OGYI-T-24042/04	LABORATOIRES BAILLEUL S.A.	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
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/271/001	OGYI-T-1278/01	CHEPLAPHARM REGISTRATION GMBH	HU
Roaccutan 20 mg lágy kapszula	EE/H/271/002	OGYI-T-1278/02	CHEPLAPHARM REGISTRATION GMBH	HU
Sotret Neo 10 mg lágy kapszula	NL/H/3739/001	OGYI-T-23222/01	Q PHARMA KFT.	HU
Sotret Neo 20 mg lágy kapszula	NL/H/3739/002	OGYI-T-23222/02	Q PHARMA KFT.	HU
Isotretinoin 10 mg soft capsules	NL/H/4820/002	PA0711/312/002	ROWEX LTD	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
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 10 mg capsule, soft	AT/H/1017/002	PA22735/002/001	GAP S.A.	IE
Isotretinoin GAP 10 mg capsule, soft.	AT/H/1017/002	PA22735/002/001	GAP S.A.	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 GAP 20 mg capsule, soft.	AT/H/1017/003	PA22735/002/002	GAP S.A.	IE
Isotretinoin GAP 20 mg capsule, soft.	AT/H/1017/003	PA22735/002/002	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
Roaccutane 10 mg soft capsules	EE/H/0271/001	PA2307/007/001	CHEPLAPHARM REGISTRATION GMBH	IE
Roaccutane 20 mg soft capsules	EE/H/0271/002	PA25306/001/002	CHEPLAPHARM REGISTRATION GMBH	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
Decutan 20 mg mjúk hylki.	DK/H/0368/002	IS/1/02/035/02	TEVA B.V	IS

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
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 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 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

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 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 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

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
Isotiorga 10 mg capsule molli	AT/H/1170/001	049901010	LABORATOIRES BAILLEUL S.A.	IT
Isotiorga 10 mg capsule molli	AT/H/1170/001	049901022	LABORATOIRES BAILLEUL S.A.	IT
Isotiorga 10 mg capsule molli	AT/H/1170/001	049901034	LABORATOIRES BAILLEUL S.A.	IT
Isotiorga 10 mg capsule molli	AT/H/1170/001	049901046	LABORATOIRES BAILLEUL S.A.	IT
Isotiorga 20 mg capsule molli	AT/H/1170/002	049901059	LABORATOIRES BAILLEUL S.A.	IT
Isotiorga 20 mg capsule molli	AT/H/1170/002	049901061	LABORATOIRES BAILLEUL S.A.	IT
Isotiorga 20 mg capsule molli	AT/H/1170/002	049901073	LABORATOIRES BAILLEUL S.A.	IT
Isotiorga 20 mg capsule molli	AT/H/1170/002	049901085	LABORATOIRES BAILLEUL S.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

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083119	DIFA COOPER S.P.A.	IT
ISOTRETINOINA DOC 10 mg capsule molli	NL/H/5841/001	051504013	DOC GENERICI S.R.L.	IT
ISOTRETINOINA DOC 20 mg capsule molli	NL/H/5841/002	051504025	DOC GENERICI S.R.L.	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
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

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 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
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/1/05/0406/002	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštosios kapsulės	EE/H/0271/002	LT/1/05/0406/006	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
Isotiorga 20 mg capsules molles	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL S.A.	LU
Isotiorga 20 mg capsules molles	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL S.A.	LU
Isotiorga 20 mg capsules molles	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL S.A.	LU
Isotiorga 20 mg capsules molles	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL S.A.	LU
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL S.A.	LU
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL S.A.	LU
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL S.A.	LU
Isotiorga 20 mg Weichkapseln	AT/H/1170/002	2022040088	LABORATOIRES BAILLEUL S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	2005060039	EUROGENERICS N.V./S.A.	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
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
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	2005060040	EUROGENERICS N.V./S.A.	LU
Isotrétinoïne EG 20 mg capsules molles	not available	2005060040	EUROGENERICS N.V./S.A.	LU
Roaccutane 10 mg capsules molles	EE/H/0271/001	2010010651	CHEPLAPHARM REGISTRATION GMBH	LU
Roaccutane 20 mg capsules molles	EE/H/0271/002	2010040736	CHEPLAPHARM REGISTRATION GMBH	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 DOC 10 mg, zachte capsules	NL/H/5841/001	RVG 131384	DOC GENERICI S.R.L.	NL
Isotretinoīne DOC 20 mg, zachte capsules	NL/H/5841/002	RVG 131385	DOC GENERICI S.R.L.	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
Isotretinoin Orifarm 10 mg kapsler, myke	DK/H/1060/001	07-5310	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 10 mg kapsler, myke	DK/H/1060/001	07-5310	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 10 mg kapsler, myke	DK/H/1060/001	07-5310	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 10 mg kapsler, myke	DK/H/1060/001	07-5310	ORIFARM GENERICS A/S	NO

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 Orifarm 10 mg kapsler, myke	DK/H/1060/001	07-5310	ORIFARM GENERICS 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
Isotretinoin Orifarm 20 mg kapsler, myke	DK/H/1060/002	07-5311	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 20 mg kapsler, myke	DK/H/1060/002	07-5311	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 20 mg kapsler, myke	DK/H/1060/002	07-5311	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 20 mg kapsler, myke	DK/H/1060/002	07-5311	ORIFARM GENERICS A/S	NO
Isotretinoin Orifarm 20 mg kapsler, myke	DK/H/1060/002	07-5311	ORIFARM GENERICS A/S	NO
Isotretinoin Sandoz 10 mg myke kapsler	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, 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
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
Axotret, 40 mg, kapsułki, miękkie	not available	27527	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
Axotret, 5 mg, kapsułki, miękkie	not available	27524	ARISTO PHARMA SP. Z O.O.	PL
Isotretinoin Aristo, 10 mg, kapsułki, miękkie	not available	27525	ARISTO PHARMA SP. Z O.O.	PL
Isotretinoin Aristo, 20 mg, kapsułki, miękkie	not available	27526	ARISTO PHARMA SP. Z O.O.	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 S.A.	PT
Isotiorga 10 mg cápsulas moles	AT/H/1170/001	5834312	LABORATOIRES BAILLEUL S.A.	PT
Isotiorga 10 mg cápsulas moles	AT/H/1170/001	5834320	LABORATOIRES BAILLEUL S.A.	PT
Isotiorga 10 mg cápsulas moles	AT/H/1170/001	5834338	LABORATOIRES BAILLEUL S.A.	PT
Isotiorga 20 mg cápsulas moles	AT/H/1170/002	5834346	LABORATOIRES BAILLEUL S.A.	PT
Isotiorga 20 mg cápsulas moles	AT/H/1170/002	5834353	LABORATOIRES BAILLEUL S.A.	PT
Isotiorga 20 mg cápsulas moles	AT/H/1170/002	5834361	LABORATOIRES BAILLEUL S.A.	PT
Isotiorga 20 mg cápsulas moles	AT/H/1170/002	5834379	LABORATOIRES BAILLEUL S.A.	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	PT/H/1878/001	4057782	GENERIS FARMACÊUTICA, S.A.	PT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
moles				
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 10 mg Cápsulas moles	PT/H/1878/001	PT/H/1878/001	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 Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	PT/H/1878/002	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína GAP 10 mg	AT/H/1017/002	AT/H/1017/002	GAP S.A.	PT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Isotretinoína GAP 10 mg	AT/H/1017/002	AT/H/1017/002	GAP S.A.	PT
Isotretinoína GAP 10 mg	AT/H/1017/002	AT/H/1017/002	GAP S.A.	PT
Isotretinoína GAP 10 mg	AT/H/1017/002	AT/H/1017/002	GAP S.A.	PT
Isotretinoína GAP 20 mg	AT/H/1017/003	AT/H/1017/003	GAP S.A.	PT
Isotretinoína GAP 20 mg	AT/H/1017/003	AT/H/1017/003	GAP S.A.	PT
Isotretinoína GAP 20 mg	AT/H/1017/003	AT/H/1017/003	GAP S.A.	PT
Isotretinoína GAP 20 mg	AT/H/1017/003	AT/H/1017/003	GAP S.A.	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 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 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	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
			FARMACÊUTICOS, S.A.	
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
Isotiorga 10 mg capsule moi	AT/H/1170/001	14554/2022/01	LABORATOIRES BAILLEUL SA	RO
Isotiorga 10 mg capsule moi	AT/H/1170/001	14554/2022/02	LABORATOIRES BAILLEUL SA	RO
Isotiorga 10 mg capsule moi	AT/H/1170/001	14554/2022/03	LABORATOIRES BAILLEUL SA	RO
Isotiorga 10 mg capsule moi	AT/H/1170/001	14554/2022/04	LABORATOIRES BAILLEUL SA	RO
Isotiorga 20 mg capsule moi	AT/H/1170/002	14555/2022/01	LABORATOIRES BAILLEUL SA	RO
Isotiorga 20 mg capsule moi	AT/H/1170/002	14555/2022/02	LABORATOIRES BAILLEUL SA	RO
Isotiorga 20 mg capsule moi	AT/H/1170/002	14555/2022/03	LABORATOIRES BAILLEUL SA	RO
Isotiorga 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

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/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
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 10 MG KAPSLAR, MJUKA	DK/H/2242/001	48555	ACTAVIS GROUP PTC EHF.	SE

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ISOTRETINOIN ACTAVIS 10 MG KAPSLAR, MJUKA	DK/H/2242/001	48555	ACTAVIS GROUP PTC EHF.	SE
ISOTRETINOIN ACTAVIS 10 MG KAPSLAR, MJUKA	DK/H/2242/001	48555	ACTAVIS GROUP PTC EHF.	SE
ISOTRETINOIN ACTAVIS 10 MG KAPSLAR, MJUKA	DK/H/2242/001	48555	ACTAVIS GROUP PTC EHF.	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 ACTAVIS 20 MG KAPSLAR, MJUKA	DK/H/2242/002	48556	ACTAVIS GROUP PTC EHF.	SE
ISOTRETINOIN ACTAVIS 20 MG KAPSLAR, MJUKA	DK/H/2242/002	48556	ACTAVIS GROUP PTC EHF.	SE
ISOTRETINOIN ACTAVIS 20 MG KAPSLAR, MJUKA	DK/H/2242/002	48556	ACTAVIS GROUP PTC EHF.	SE
ISOTRETINOIN ACTAVIS 20 MG KAPSLAR, MJUKA	DK/H/2242/002	48556	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

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Isotretinoin Orifarm 10 mg kapslar, mjuka	DK/H/1060/001	57967	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 10 mg kapslar, mjuka	DK/H/1060/001	57967	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 10 mg kapslar, mjuka	DK/H/1060/001	57967	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 10 mg kapslar, mjuka	DK/H/1060/001	57967	ORIFARM GENERICS 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
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	57968	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	57968	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	57968	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 20 mg kapslar, mjuka	DK/H/1060/002	57968	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

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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
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 S.A.	SK
Isotiorga 20 mg mäkke kapsuly	AT/H/1170/002	46/0115/22-S	LABORATOIRES BAILLEUL S.A.	SK
Isotiorga 20 mg mäkke kapsuly	AT/H/1170/002	46/0115/22-S	LABORATOIRES BAILLEUL S.A.	SK
Isotiorga 20 mg mäkke kapsuly	AT/H/1170/002	46/0115/22-S	LABORATOIRES BAILLEUL S.A.	SK
Isotretinoin Actavis 10 mg mäkke kapsuly	DK/H/2242/001	46/0418/13-S	TEVA B.V	SK
Isotretinoin Actavis 10 mg mäkke kapsuly	DK/H/2242/001	46/0418/13-S	TEVA B.V	SK
Isotretinoin Actavis 10 mg mäkke kapsuly	DK/H/2242/001	46/0418/13-S	TEVA B.V	SK
Isotretinoin Actavis 10 mg mäkke kapsuly	DK/H/2242/001	46/0418/13-S	TEVA B.V	SK
Isotretinoin Actavis 10 mg mäkke kapsuly	DK/H/2242/001	46/0418/13-S	TEVA B.V	SK
Isotretinoin Actavis 10 mg mäkke kapsuly	DK/H/2242/001	46/0418/13-S	TEVA B.V	SK
Isotretinoin Actavis 20 mg mäkke kapsuly	DK/H/2242/002	46/0419/13-S	TEVA B.V	SK
Isotretinoin Actavis 20 mg mäkke kapsuly	DK/H/2242/002	46/0419/13-S	TEVA B.V	SK
Isotretinoin Actavis 20 mg mäkke kapsuly	DK/H/2242/002	46/0419/13-S	TEVA B.V	SK

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Isotretinoin Actavis 20 mg mäkke kapsuly	DK/H/2242/002	46/0419/13-S	TEVA B.V	SK
Isotretinoin Actavis 20 mg mäkke kapsuly	DK/H/2242/002	46/0419/13-S	TEVA B.V	SK
Isotretinoin Actavis 20 mg mäkke 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 55612/ 0041	ENNOGEN IP LIMITED	XI
Isotretinoin 20 mg soft capsules	NL/H/3739/002	PL 31750/0100	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	XI
Isotretinoin 20 mg soft capsules	not available	PL 55612/0042	ENNOGEN IP LIMITED	XI
Isotretinoin 30 mg soft capsules	not available	PL 55612/ 0080	ENNOGEN IP LIMITED	XI
Isotretinoin 5 mg capsules	UK/H/7020/001	PL 55612/0043	ENNOGEN IP LIMITED	XI
Roaccutane 10 mg soft capsules	not available	PL 45043/0137	NEON HEALTHCARE LIMITED	XI
Roaccutane 20 mg soft capsules	not available	PL 45043/0138	NEON HEALTHCARE LIMITED	XI