12 December 2018
EMA/25207/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: isotretinoin (oral formulations)

Procedure no.: PSUSA/00010488/201805

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525
Send a question via our website www.ema.europa.eu/contact

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
Accuran, 10 mg/cap, καψάκιο, μαλακό	not available	18066/21-03-2012	NEXUS MEDICALS S.A.	GR
Accuran, 20 mg/cap, καψάκιο, μαλακό	not available	18066/21-03-2012	NEXUS MEDICALS S.A.	GR
Accutin, kapsler, bløde	not available	31531	SANDOZ A/S	DK
Accutin, kapsler, bløde	not available	31532	SANDOZ A/S	DK
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
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
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
ACNETRAIT 10 mg, capsule molle	not available	NL 26226	ARROW GENERIQUES	FR
ACNETRAIT 20 mg, capsule molle	not available	NL 26227	ARROW GENERIQUES	FR
ACNETRAIT 40 mg, capsule molle	not available	NL 36266	ARROW GENERIQUES	FR
ACNETRAIT 5 mg, capsule molle	not available	NL 36265	ARROW GENERIQUES	FR
ACNOGEN/GENEPHARM	not available	38591/10/18-04-2011	GENEPHARM S.A.	GR
ACNOGEN/GENEPHARM	not available	38594/10/18-04-2011	GENEPHARM S.A.	GR
A-CNOTREN 10 mg καψάκια	DK/H/0889/001	45/16-01-2012	PHARMATHEN HELLAS S.A.	GR
A-CNOTREN 10 mg καψάκια	DK/H/0889/001	45/16-01-2012	PHARMATHEN HELLAS S.A.	GR
A-CNOTREN 20 mg καψάκια	not available	45047/10/18-04-2012	PHARMATHEN HELLAS 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
ACTAVEN, 10 MG, KAPSULKI, MIEKKIE	DK/H/2242/001	21632	ACTAVIS GROUP PTC EHF.	PL
ACTAVEN, 10 MG, KAPSULKI, MIEKKIE	DK/H/2242/001	21632	ACTAVIS GROUP PTC EHF.	PL
Actaven, 20 mg, kapsułki, miękkie	DK/H/2242/002	21633	ACTAVIS GROUP PTC EHF.	PL
Actaven, 20 mg, kapsułki, miękkie	DK/H/2242/002	21633	ACTAVIS GROUP PTC EHF.	PL
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
Aknenormin 10 10 mg mäkké kapsuly	DE/H/1702/001/MR	46/0130/05-S	ALMIRALL HERMAL GMBH	SK
Aknenormin 10 mg lágy kapszula	DE/H/1702/001	OGYI-T-10170/01	ALMIRALL HERMAL GMBH	HU
Aknenormin 10 mg měkké tobolky	DE/H/1702/001	46/138/05-C	ALMIRALL HERMAL GMBH	CZ
Aknenormin 10 mg Weichkapseln	DE/H/1702/001/MR	55003.00.00	ALMIRALL HERMAL GMBH	DE
Aknenormin 20 20 mg mäkké kapsuly	DE/H/1702/002/MR	46/0129/05-S	ALMIRALL HERMAL GMBH	SK
Aknenormin 20 mg lágy kapszula	DE/H/1702/002	OGYI-T-10171/01	ALMIRALL HERMAL GMBH	HU
Aknenormin 20 mg měkké tobolky	DE/H/1702/002/MR	46/139/05-C	ALMIRALL HERMAL GMBH	CZ
Aknenormin 20 mg Weichkapseln	DE/H/1702/002/MR	55003.01.00	ALMIRALL HERMAL GMBH	DE
Aknenormin, 10 mg, kapsulki miękkie	DE/H/1702/001/MR	11427	ALMIRALL HERMAL GMBH	PL
Aknenormin, 20 mg, kapsułki miękkie	DE/H/1702/002/MR	11426	ALMIRALL HERMAL GMBH	PL
Axotret 10 mg, kapsułki, miękkie	not available	11318	AXXON 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 20 mg, kapsułki, miękkie	not available	11319	AXXON SP. Z O.O.	PL
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
CONTRACNE 10 mg, capsule molle	not available	34009 358 120 4 9	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 10 mg, capsule molle	not available	34009 358 121 0 0	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 10 mg, capsule molle	not available	34009 358 122 7 8	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 116 7 7	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 117 3 8	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 20 mg, capsule molle	not available	34009 358 119 6 7	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 40 mg, capsule molle	not available	34009 367 884 3 5	LABORATOIRES BAILLEUL SA	FR
CONTRACNE 40 mg, capsule molle	not available	34009 367 888 9 3	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
Curacne 10 mg kapsułki, miękkie	FR/H/0250/002	11919	PIERRE FABRE DERMATOLOGIE	PL
Curacne 10 mg kapsułki,	FR/H/0250/002	11919	PIERRE FABRE	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			DERMATOLOGIE	
CURACNÉ 10 mg měkká tobolka	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg měkká tobolka	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg měkká tobolka	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg měkká tobolka	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg měkká tobolka	FR/H/0250/002	46/056/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 129 1 9	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 10 mg, capsule molle	FR/H/0250/002	34009 358 131 6 9	PIERRE FABRE DERMATOLOGIE	FR
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
Curacne 20 mg kapsułki, miękkie	FR/H/0250/003	11918	PIERRE FABRE DERMATOLOGIE	PL
Curacne 20 mg kapsułki, miękkie	FR/H/0250/003	11918	PIERRE FABRE DERMATOLOGIE	PL
CURACNÉ 20 mg měkká tobolka	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkká tobolka	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkká tobolka	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkká tobolka	FR/H/0250/003	46/054/06-C	PIERRE FABRE DERMATOLOGIE	CZ
CURACNÉ 20 mg měkká	FR/H/0250/003	46/054/06-C	PIERRE FABRE	CZ

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
tobolka			DERMATOLOGIE	
CURACNÉ 20 mg, capsule molle	FR/H/0250/003	34009 358 115 0 9	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
Curacne 40 mg kapsułki, miękkie	FR/H/0250/004	14709	PIERRE FABRE DERMATOLOGIE	PL
CURACNÉ 40 mg mäkké kapsuly	FR/H/0250/004	46/0119/08-S	PIERRE FABRE DERMATOLOGIE	SK
CURACNÉ 40 mg, capsule molle	FR/H/0250/004	34009 367 603 4 9	PIERRE FABRE DERMATOLOGIE	FR
CURACNÉ 40 mg, capsule molle	FR/H/0250/004	0472984	PIERRE FABRE DERMATOLOGIE	LU
CURACNÉ 40 mg, měkká tobolka	FR/H/0250/004	46/095/08-C	PIERRE FABRE DERMATOLOGIE	CZ
Curacne 5 mg kapsułki, miękkie	FR/H/0250/001	11920	PIERRE FABRE DERMATOLOGIE	PL
CURACNÉ 5 mg, capsule molle	FR/H/0250/001	34009 358 123 3 9	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
CURACNÉ Gé 10 mg,	FR/H/0250/002	0427913	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 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	0427961	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 DERMATOLOGIE	LU
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	0427846	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
Decutan 10 mg hylki, mjúk	DK/H/0368/001	IS/1/02/035/01	ACTAVIS GROUP PTC EHF.	IS
Decutan 10 mg hylki, mjúk	DK/H/0368/001	IS/1/02/035/01	ACTAVIS GROUP PTC EHF.	IS
Decutan 10 mg Soft	not available	MA628/17401	ACTAVIS GROUP PTC EHF.	MT

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
Capsules				
Decutan 20 mg hylki, mjúk	DK/H/0368/002	IS/1/02/035/02	ACTAVIS GROUP PTC EHF.	IS
Decutan 20 mg hylki, mjúk	DK/H/0368/002	IS/1/02/035/02	ACTAVIS GROUP PTC EHF.	IS
Decutan 20 mg Soft Capsules	not available	MA628/17402	ACTAVIS GROUP PTC EHF.	MT
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 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 FARMACEUTICAS CENTRUM, S.A	ES
FLEXRESAN 20 mg cápsulas blandas	not available	66.159	ESPECIALIDADES FARMACEUTICAS CENTRUM, S.A	ES
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 10 mg lágy	DK/H/2242/001	OGYI-T-22560/02	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-22560/03	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-22560/12	ACTAVIS GROUP PTC EHF.	HU
Inerta 20 mg lágy kapszula	DK/H/2242/002	OGYI-T-22560/06-10	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-22560/06-10	ACTAVIS GROUP PTC EHF.	HU
Isdiben 10 mg cápsulas blandas	UK/H/0504/002	66.121	ISDIN, S.A.	ES
Isdiben 10 mg capsule molli	UK/H/3577/002	041853045	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	UK/H/3577/002	041853058	ISDIN S.R.L.	IT
Isdiben 10 mg capsule molli	UK/H/3577/002	041853060	ISDIN S.R.L.	IT
Isdiben 20 mg cápsulas blandas	UK/H/0504/003	66.122	ISDIN, S.A.	ES
Isdiben 20 mg capsule molli	UK/H/3577/003	041853072	ISDIN S.R.L.	IT
Isdiben 20 mg capsule molli	UK/H/3577/003	041853084	ISDIN S.R.L.	IT
Isdiben 20 mg capsule	UK/H/3577/003	041853096	ISDIN S.R.L.	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
molli				
Isdiben 40 mg cápsulas blandas	UK/H/3577/004	76.045	ISDIN, S.A.	ES
Isdiben 40 mg capsule molli	UK/H/3577/004	041853108	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	UK/H/3577/004	041853110	ISDIN S.R.L.	IT
Isdiben 40 mg capsule molli	UK/H/3577/004	041853122	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	UK/H/3577/001	041853019	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	UK/H/3577/001	041853021	ISDIN S.R.L.	IT
Isdiben 5 mg capsule molli	UK/H/3577/001	041853033	ISDIN S.R.L.	IT
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 blandas	FR/H/0250/001	67.464	PIERRE FABRE IBERICA, S.A.	ES
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, capsules molles	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	BE
ISOCURAL 10 mg, zachte	FR/H/0250/002	BE280411	PIERRE FABRE BENELUX	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
capsules				
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, 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 20 mg, zachte capsules	FR/H/0250/003	BE280427	PIERRE FABRE BENELUX	BE
ISOCURAL 40 mg, capsules molles	FR/H/0250/004	BE 334047	PIERRE FABRE BENELUX S.A.	BE
ISOCURAL 40 mg, zachte capsules	FR/H/0250/004	BE334047	PIERRE FABRE BENELUX	BE
ISOCURAL 5 mg,	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	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
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, 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
ISOCURAL 5 mg, zachte capsules	FR/H/0250/001	BE280402	PIERRE FABRE BENELUX	BE
Isoderm 10 mg	not available	48903.00.00	DERMAPHARM AG	DE
Isoderm 20 mg	not available	48903.01.00	DERMAPHARM AG	DE
Isoderm, 10 mg, kapsułki, miękkie	not available	18136	SUN-FARM SP. Z.O.O.	PL
Isoderm, 20 mg, kapsulki, miekkie	not available	18137	SUN-FARM SP. Z.O.O.	PL
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
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
ISOMACNE, BLØDE KAPSLER	DK/H/0368/002	33137	ACTAVIS GROUP PTC EHF.	DK

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Isomacne, bløde kapsler	DK/H/0368/001	33136	ACTAVIS GROUP PTC EHF.	DK
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
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
Isotret-HEXAL 10 mg Kapseln	DK/H/0300/001	54100.00.00	HEXAL AG	DE
Isotret-HEXAL 20 mg Kapseln	DK/H/0300/002	54100.01.00	HEXAL AG	DE
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 “Actavis”, bløde kapsler	DK/H/0297/002	31472	ACTAVIS GROUP PTC EHF.	DK
Isotretinoin “Actavis”, bløde kapsler	DK/H/0297/001	31471	ACTAVIS GROUP PTC EHF.	DK
Isotretinoin “Actavis”,	DK/H/0297/002	31472	ACTAVIS GROUP PTC EHF.	DK

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
bløde kapsler				
Isotretinoin “Actavis”, bløde kapsler	DK/H/0297/001	31471	ACTAVIS GROUP PTC EHF.	DK
ISOTRETINOIN ”ACTAVIS”, BLØDE KAPSLER 40 MG	DK/H/1747/001	37461	ACTAVIS GROUP PTC EHF.	DK
ISOTRETINOIN ”ACTAVIS”, BLØDE KAPSLER 40 MG	DK/H/1747/001	37461	ACTAVIS GROUP PTC EHF.	DK
Isotretinoin ”Difa Cooper”, bløde kapsler	DK/H/1749/001	37463	DIFA COOPER S.P.A.	DK
Isotretinoin ”ratiopharm”, bløde kapsler	DK/H/0298/001	31473	RATIOPHARM GMBH	DK
Isotretinoin ”ratiopharm”, bløde kapsler	DK/H/0298/002	31474	RATIOPHARM GMBH	DK
Isotretinoin 10 mg Capsules	NL/H/0593/001	PL 04416/1032	SANDOZ LTD	UK
Isotretinoin 10 mg Capsules	not available	PL 14894/0161	RANBAXY (UK) LIMITED	UK
Isotretinoin 10 mg Soft Capsules	UK/H/3577/002	PL 04569/1344	GENERICS [UK] LIMITED	UK
Isotretinoin 10 mg Soft Capsules	UK/H/0504/002	PL 04569/0725	GENERICS [UK] LIMITED	UK
Isotretinoin 10 mg soft capsules	NL/H/3739/001	PL 31750/0099	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	UK
Isotretinoin 20 mg Capsules	NL/H/0593/002	PL 04416/1033	SANDOZ LTD	UK
Isotretinoin 20 mg Capsules	not available	PL 14894/0162	RANBAXY (UK) LIMITED	UK
Isotretinoin 20 mg Soft Capsules	UK/H/3577/003	PL 04569/1345	GENERICS [UK] LIMITED	UK
Isotretinoin 20 mg Soft Capsules	UK/H/0504/003	PL 04569/0724	GENERICS [UK] LIMITED	UK

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Isotretinoin 20 mg soft capsules	NL/H/3739/002	PL 31750/0100	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	UK
Isotretinoin 20mg Capsules	not available	PL 16853/0133	ALLIANCE PHARMACEUTICALS LTD	UK
Isotretinoin 40 mg Soft Capsules	UK/H/3577/004	PL 04569/1346	GENERICS [UK] LIMITED	UK
Isotretinoin 5 mg Soft Capsules	UK/H/3577/001	PL 04569/1343	GENERICS [UK] LIMITED	UK
Isotretinoin 5 mg Soft Capsules	UK/H/0504/001	PL 04569/0726	GENERICS [UK] LIMITED	UK
Isotretinoin 5mg Capsules	not available	PL 16853/0132	ALLIANCE PHARMACEUTICALS LTD	UK
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 mäkké kapsuly	DK/H/2242/001	46/0418/13-S	ACTAVIS GROUP PTC EHF.	SK
Isotretinoin Actavis 10 mg mäkké kapsuly	DK/H/2242/001	46/0418/13-S	ACTAVIS GROUP PTC EHF.	SK
Isotretinoin Actavis 10 mg, kapseli, pehmeä	DK/H/0297/001	17179	ACTAVIS GROUP PTC EHF.	FI
Isotretinoin Actavis 10 mg, kapseli, pehmeä	DK/H/0297/001	17179	ACTAVIS GROUP PTC EHF.	FI
ISOTRETINOIN ACTAVIS 20 MG 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 MÄKKÉ KAPSULY	DK/H/2242/002	46/0419/13-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
ISOTRETINOIN ACTAVIS 20 MG, KAPSELI,	DK/H/0297/002	17180	ACTAVIS GROUP PTC EHF.	FI

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
PEHMEÄ				
ISOTRETINOIN ACTAVIS 20 MG, KAPSELI, PEHMEÄ	DK/H/0297/002	17180	ACTAVIS GROUP PTC EHF.	FI
ISOTRETINOIN ACTAVIS 40 MG, KAPSELI, PEHMEÄ	DK/H/1747/001	27968	ACTAVIS GROUP PTC EHF.	FI
ISOTRETINOIN ACTAVIS 40 MG, KAPSELI, PEHMEÄ	DK/H/1747/001	27968	ACTAVIS GROUP PTC EHF.	FI
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 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
Isotretinoin Orifarm 10 mg kapslar, mjuka	DK/H/1060/001	57967	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 10 mg kapsler, myke	DK/H/1060/001	07-5310	ORIFARM GENERICS A/S	NO
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	57968	ORIFARM GENERICS A/S	SE
Isotretinoin Orifarm 20 mg kapsler, myke	DK/H/1060/002	07-5311	ORIFARM GENERICS A/S	NO
Isotretinoin Orion 20 mg pehmeat kapselit	DK/H/0889/002	21907	PHARMATHEN S.A.	FI
Isotretinoin PUREN 10 mg Weichkapseln	PT/H/1878/001	54253.00.00	PUREN PHARMA GMBH & CO. KG	DE
Isotretinoin PUREN 20 mg Weichkapseln	PT/H/1878/002	54253.01.00	PUREN PHARMA GMBH & CO. KG	DE

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 20 mg kapseli, pehmeä	FI/H/0993/002	17152	RATIOPHARM GMBH	FI
Isotretinoin ratiopharm 20 mg mjúk hylki	IS/H/0290/001	IS/1/14/036/01	RATIOPHARM GMBH	IS
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057584	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057683	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057782	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057881	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	4057980	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 10 mg Cápsulas moles	PT/H/1878/001	PT/H/1878/001	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058087	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058186	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058285	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058384	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	4058483	AUROVITAS UNIPESSOAL, LDA.	PT
Isotretinoína Aurovitas 20 mg Cápsulas moles	PT/H/1878/002	PT/H/1878/002	AUROVITAS UNIPESSOAL, LDA.	PT
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

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	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
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 10 mg capsule molli	DK/H/0298/001	036083018	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001	036083020	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001	036083032	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001	036083044	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 10 mg capsule molli	DK/H/0298/001-002	036083057/M	DIFA COOPER S.P.A.	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083069/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083071/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083083/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083095/M	DIFA COOPER S.P.A.	IT
Isotretinoina Difa Cooper 20 mg capsule molli	DK/H/0298/002	036083107/M	DIFA COOPER S.P.A.	IT
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
Isotretinoína Generis 10 mg Cápsulas moles	not available	5503297	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Generis 10 mg Cápsulas moles	not available	4882296	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Generis 10 mg Cápsulas moles	not available	5161591	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Generis 10 mg Cápsulas moles	not available	5113923	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Generis 20 mg Cápsulas moles	not available	5503396	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Generis 20 mg Cápsulas moles	not available	4882395	GENERIS FARMACÊUTICA, S.A.	PT
Isotretinoína Generis 20 mg Cápsulas moles	not available	5161492	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
Isotretinoína Generis 20 mg Cápsulas moles	not available	5113931	GENERIS FARMACÊUTICA, 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 FARMACÊUTICOS, S.A.	PT
Isotretinoína Orotrex 20 mg cápsulas moles	not available	4882593	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Isotretinoína Orotrex 20 mg cápsulas moles	not available	5174891	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Isotretinoína Orotrex, 5 mg cápsulas moles	not available	5750518	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Isotretinoína Orotrex, 5 mg cápsulas moles	not available	5750526	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT

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 SUN 10 mg cápsulas blandas	NL/H/3739/001	82566	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES
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
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
Isotretinoína SUN 20 mg cápsulas blandas	NL/H/3739/002	82567	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES
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
Isotretinoïne Aurobindo 10 mg, capsules	PT/H/1878/001	RVG 27577	AUROBINDO PHARMA B.V.	NL
Isotretinoïne Aurobindo 20 mg, capsules	PT/H/1878/002	RVG 27578	AUROBINDO PHARMA B.V.	NL
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	BE266296	EUROGENERICS N.V./S.A.	BE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Isotrétinoïne EG 10 mg capsules molles	BE/H/0193/001	0019/05060039	EUROGENERICS N.V./S.A.	LU
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
Isotretinoïne EG 20 mg capsules molles	BE/H/0193/002	BE270173	EUROGENERICS N.V./S.A.	BE
Isotrétinoïne EG 20 mg capsules molles	BE/H/0193/002	0019/05060040	EUROGENERICS N.V./S.A.	LU
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
Isotretinoïne Mylan 10 mg, zachte capsules	UK/H/0504/002	RVG 27573	MYLAN B.V.	NL
Isotretinoïne Mylan 20 mg, zachte capsules	UK/H/0504/003	RVG 27574	MYLAN B.V.	NL
ISOTRETINOÏNE SANDOZ 10 MG, CAPSULES	NL/H/0593/001	RVG 26547	SANDOZ B.V.	NL
Isotretinoïne Sandoz 20 mg zachte capsules	NL/H/0593/002	BE291137	SANDOZ N.V.	BE
ISOTRETINOÏNE SANDOZ 20 MG, CAPSULES	NL/H/0593/002	RVG 26548	SANDOZ B.V.	NL
Isotretinoïne SUN 10 mg, zachte capsules	NL/H/3739/001	RVG 119052	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Isotretinoïne SUN 20 mg, zachte capsules	NL/H/3739/002	RVG 119053	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
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

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-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/05	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/04	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/02	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/01	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 10 mg lágy kapszula	not available	OGYI-T-20238/03	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/10	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/06	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/07	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/09	TEVA MAGYARORSZÁG ZRT	HU
Isotretinoin-Teva 20 mg lágy kapszula	not available	OGYI-T-20238/08	TEVA MAGYARORSZÁG ZRT	HU
ISOTROIN® 10mg καψάκια μαλακά	not available	20695	IASIS PHARMA	CY
ISOTROIN® 10mg καψάκια μαλακά	not available	76447/10-11-11	IASIS PHARMA	GR
ISOTROIN® 20mg καψάκια μαλακά	not available	20693	IASIS PHARMA	CY
ISOTROIN® 20mg καψάκια μαλακά	not available	76449/10-11-11	IASIS PHARMA	GR
ISOTROIN® 40mg καψάκια μαλακά	not available	S00714	IASIS PHARMA	CY
ISOTROIN® 40mg καψάκια μαλακά	not available	78135/10-11-11	IASIS PHARMA	GR
Izotek, 10 mg, kapsułki, miękkie	DK/H/0889/001	12350	PHARMASWISS ČESKÁ REPUBLIKA S.R.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
Izotek, 20 mg, kapsułki, miękkie	DK/H/0889/002	12349	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
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
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
Pharmiso, bløde kapsler	DK/H/0300/002	31478	HEXAL AG	DK
Pharmiso, bløde kapsler	DK/H/0300/001	31477	HEXAL AG	DK
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

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
PROCUTA 10 mg, capsule molle	not available	34009 358 109 0 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 10 mg, capsule molle	not available	34009 357 839 5 0	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 104 9 6	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 357 836 6 0	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 105 5 7	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 358 106 1 8	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 20 mg, capsule molle	not available	34009 357 837 2 1	LABORATOIRES EXPANSCIENCE	FR
PROCUTA 40 mg, capsule molle	not available	34009 367 880 8 4	LABORATOIRES EXPANSCIENCE	FR
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
Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
REDUCAR 10mg μαλακό καψάκιο	not available	41918/14-6-2013	GAP S.A.	GR
REDUCAR 20mg μαλακό καψάκιο	not available	39324/14-6-2013	GAP S.A.	GR

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Rizuderm 20mg Capsules	not available	PL 16853/0133	ALLIANCE PHARMACEUTICALS LTD	UK
Rizuderm 5mg Capsules	not available	PL 16853/0132	ALLIANCE PHARMACEUTICALS LTD	UK
Roaccutan 10 mg lágy kapszula	UK/H/0666/001	OGYI-T-1278/01	ROCHE (MAGYARORSZÁG) KFT	HU
Roaccutan 20 mg lágy kapszula	UK/H/0666/002	OGYI-T-1278/02	ROCHE (MAGYARORSZÁG) KFT	HU
Roaccutane 10 mg capsule moi	not available	7661/2015/01	ROCHE ROMANIA SRL	RO
Roaccutane 10 mg capsules molles	UK/H/0666/001	BE130611	N.V. ROCHE S.A.	BE
Roaccutane 10 mg capsules molles	UK/H/0666/001	2010010651	N.V. ROCHE S.A.	LU
Roaccutane 10 mg mehke kapsule	UK/H/0666/01-02	H/96/01368/002	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg mehke kapsule	UK/H/0666/01-02	H/96/01368/003	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg mehke kapsule	UK/H/0666/01-02	H/96/01368/004	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg mehke kapsule	UK/H/0666/001	H/96/01368/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 10 mg meke kapsule	not available	HR-H-462694255	ROCHE D.O.O.	HR
Roaccutane 10 mg mīkstās kapsulas	UK/H/0666/001	05-0517	ROCHE LATVIJA SIA	LV
Roaccutane 10 mg minkštos kapsulės	UK/H/0666/001/	LT/1/05/0406/003	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštos kapsulės	UK/H/0666/001/	LT/1/05/0406/001	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštos kapsulės	UK/H/0666/001/	LT/1/05/0406/004	UAB "ROCHE LIETUVA"	LT
Roaccutane 10 mg minkštos kapsulės	UK/H/0666/001	LT/1/05/0406/002	UAB "ROCHE LIETUVA"	LT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Roaccutane 10 mg Soft Capsules	UK/H/0666/001	PA 50/53/5	ROCHE PRODUCTS LTD	IE
Roaccutane 10 mg soft capsules	UK/H/0666/01-02	PL 00031/0617	ROCHE PRODUCTS LTD	UK
Roaccutane 10 mg Weichkapseln	UK/H/0666/001	BE130611	N.V. ROCHE S.A.	BE
Roaccutane 10 mg Weichkapseln	UK/H/0666/001	2010010651	N.V. ROCHE S.A.	LU
Roaccutane 10 mg zachte capsules	UK/H/0666/001	BE130611	N.V. ROCHE S.A.	BE
Roaccutane 10 mg, pehmekapslid	UK/H/0666/001	052294	ROCHE EESTI OÜ	EE
Roaccutane 20 mg capsules molles	UK/H/0666/002	BE130627	N.V. ROCHE S.A.	BE
Roaccutane 20 mg capsules molles	UK/H/0666/002	2010040736	N.V. ROCHE S.A.	LU
Roaccutane 20 mg mehke kapsule	UK/H/0666/01-02	H/96/01368/007	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	UK/H/0666/01-02	H/96/01368/008	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	UK/H/0666/01-02	H/96/01368/006	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mehke kapsule	UK/H/0666/002	H/96/01368/005	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Roaccutane 20 mg mīkstās kapsulas	UK/H/0666/002	05-0518	ROCHE LATVIJA SIA	LV
Roaccutane 20 mg minkštos kapsulės	UK/H/0666/002	LT/1/05/0406/006	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštos kapsulės	UK/H/0666/002/	LT/1/05/0406/008	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštos kapsulės	UK/H/0666/002/	LT/1/05/0406/007	UAB "ROCHE LIETUVA"	LT
Roaccutane 20 mg minkštos kapsulės	UK/H/0666/002/	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
Roaccutane 20 mg Soft Capsules	UK/H/0666/002	PA 50/53/4	ROCHE PRODUCTS LTD	IE
Roaccutane 20 mg soft capsules	UK/H/0666/01-02	PL 00031/0160	ROCHE PRODUCTS LTD	UK
Roaccutane 20 mg Weichkapseln	UK/H/0666/01-02	BE130627	N.V. ROCHE S.A.	BE
Roaccutane 20 mg Weichkapseln	UK/H/0666/002	2010040736	N.V. ROCHE S.A.	LU
Roaccutane 20 mg zachte capsules	UK/H/0666/002	BE130627	N.V. ROCHE S.A.	BE
Roaccutane 20 mg, pehmekapslid	UK/H/0666/002	404002	ROCHE EESTI OÜ	EE
ROCNE	not available	87229/7-12-2009	PHARMATHEN S.A.	GR
ROCNE	not available	87230/7-12-2009	PHARMATHEN S.A.	GR
Rotaxin 10mg soft gelatin capsules	not available	21122	HADJICONSTANTINOU BROS	CY
Rotaxin 20mg soft gelatin capsules	not available	21123	HADJICONSTANTINOU BROS	CY
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/01	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/02	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/03	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/04	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/05	TERAPIA S.A.	RO
Sotret 10 mg capsule moi	NL/H/3739/001/DC	10194/2017/06	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/01	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/02	TERAPIA S.A.	RO

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/03	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/04	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/05	TERAPIA S.A.	RO
Sotret 20 mg capsule moi	NL/H/3739/002/DC	10195/2017/06	TERAPIA S.A.	RO
Sotret Neo 10 mg lágy kapszula	NL/H/3739/001	OGYI-T-23222/01	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HU
Sotret Neo 20 mg lágy kapszula	NL/H/3739/002	OGYI-T-23222/02	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HU
Sotret, 10 mg, kapsułki miękkie	NL/H/3739/001	24226	RANBAXY POLAND SP. ZO.O	PL
Sotret, 20 mg, kapsułki miękkie	NL/H/3739/002	24227	RANBAXY POLAND SP. ZO.O	PL
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
Tretoskin, 10 mg, kapsułki miękkie	not available	12054	VITAMA S.A.	PL
Tretoskin, 10 mg, kapsułki miękkie	not available	12054	VITAMA S.A.	PL
Tretoskin, 20 mg, kapsułki miękkie	not available	12053	VITAMA S.A.	PL
Tretoskin, 20 mg, kapsułki miękkie	not available	12053	VITAMA S.A.	PL
Tretoskin, 20 mg, kapsułki miękkie	not available	12053	VITAMA S.A.	PL
Роакутан 20 mg капсули, меки	not available	20030084	ROCHE BULGARIA EOOD	BG