



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2019
EMA/437626/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: acitretin

Procedure no.: PSUSA/00000051/201810

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Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
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
Neotigason 10 mg Cápsulas	not available	8756403	GENERIS FARMACÊUTICA, S.A.	PT
Neotigason 10 mg Cápsulas	not available	8756411	GENERIS FARMACÊUTICA, S.A.	PT
Neotigason 25 mg Cápsulas	not available	8756437	GENERIS FARMACÊUTICA, S.A.	PT
Neotigason 25 mg Cápsulas	not available	8756429	GENERIS FARMACÊUTICA, S.A.	PT
Acitretine CF 10 mg, capsules	NL/H/1959/001	RVG 107065	CENTRAFARM B.V.	NL
Acitretin 10 mg Capsules	NL/H/1959/001	PL 06831/0251	GENUS PHARMACEUTICALS LIMITED	UK
Acitretine CF 25 mg, capsules	NL/H/1959/002	RVG 107066	CENTRAFARM B.V.	NL
Acitretin 25 mg Capsules	NL/H/1959/002	PL 06831/0252	GENUS PHARMACEUTICALS 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
NEOTIGASON®10 mg trde kapsule	not available	H/96/01103/001	ACTAVIS GROUP PTC EHF.	SI
NEOTIGASON®25 mg trde kapsule	not available	H/96/01103/002	ACTAVIS GROUP PTC EHF.	SI
Acicutan 10 mg Hartkapseln	DE/H/5797/001/DC	81208.00.00	DERMAPHARM AG	DE
Acicutan 25 mg Hartkapseln	DE/H/5797/002/DC	81209.00.00	DERMAPHARM AG	DE
Acitren, 10 mg, kapsułki twarde	DE/H/5797/001	18728	SUN-FARM SP. Z.O.O.	PL
Acitren, 25 mg, kapsułki twarde	DE/H/5797/002	18729	SUN-FARM SP. Z.O.O.	PL
Neotigason 10 mg kemény kapszula	not available	OGYI-T-4469/01	ACTAVIS GROUP PTC EHF.	HU
Neotigason 25 mg kemény kapszula	not available	OGYI-T-4469/02	ACTAVIS GROUP PTC EHF.	HU
Neotigason 10 mg Kapseln	not available	1-18708	ACTAVIS GROUP PTC EHF.	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
Neotigason 25 mg Kapseln	not available	1-18709	ACTAVIS GROUP PTC EHF.	AT
NEOTIGASON 10MG	not available	46/0661/95-S	ACTAVIS GROUP PTC EHF.	SK
NEOTIGASON 25MG tvrdé kapsuly	not available	46/0263/15-S	ACTAVIS GROUP PTC EHF.	SK
Acitretin 10mg Capsules	not available	PL 20117/0265	MORNINGSIDE HEALTHCARE LTD	UK
Acitretin 25mg Capsules	not available	PL 20117/0266	MORNINGSIDE HEALTHCARE LTD	UK
Neotigason 25 mg, capsules	not available	RVG 13104	AUROBINDO PHARMA B.V.	NL
Neotigason 10 mg, capsules	not available	RVG 13103	AUROBINDO PHARMA B.V.	NL
Neotigason 25 mg harde capsules	not available	BE144602	AUROBINDO PHARMA B.V.	BE
Neotigason 10 mg harde capsules	not available	BE144706	AUROBINDO PHARMA B.V.	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
Neotigason 25 mg Hartkapseln	not available	0148013	AUROBINDO PHARMA B.V.	LU
Neotigason 10 mg Hartkapseln	not available	0147999	AUROBINDO PHARMA B.V.	LU
Neotigason 10 mg gélules	not available	0147999	AUROBINDO PHARMA B.V.	LU
Neotigason 25 mg gélules	not available	0148013	AUROBINDO PHARMA B.V.	LU
Neotigason 10 mg Hartkapseln	not available	BE144706	AUROBINDO PHARMA B.V.	BE
Neotigason 25 mg Hartkapseln	not available	BE144602	AUROBINDO PHARMA B.V.	BE
Neotigason 25 mg gélules	not available	BE144602	AUROBINDO PHARMA B.V.	BE
Neotigason 10 mg gélules	not available	BE144706	AUROBINDO PHARMA B.V.	BE
Neotigason 10 mg capsule	not available	9699/2017/01	ACTAVIS GROUP PTC EHF.	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
Neotigason 10 mg tvrde kapsule	not available	HR-H-047281874	ACTAVIS GROUP PTC EHF.	HR
Neotigason 25 mg tvrde kapsule	not available	HR-H-770001325	ACTAVIS GROUP PTC EHF.	HR
Neotigason, hårde kapsler	not available	13124	ACTAVIS GROUP PTC EHF.	DK
Neotigason	not available	13125	ACTAVIS GROUP PTC EHF.	DK
Acitretin "Orifarm", hårde kapsler	DK/H/2552/001	56275	ORIFARM GENERICS A/S	DK
Acitretin "Orifarm", hårde kapsler	DK/H/2552/002	56280	ORIFARM GENERICS A/S	DK
Acitretin Orifarm 10 mg kapsler, harde	DK/H/2552/001	15-10784	ORIFARM GENERICS A/S	NO
Acitretin Orifarm 25 mg kapsler, harde	DK/H/2552/002	15-10785	ORIFARM GENERICS A/S	NO
Acitretin Orifarm 25 mg hårda kapslar	DK/H/2552/002	53203	ORIFARM GENERICS A/S	SE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Acitretin Orifarm 10 mg hårda kapslar	DK/H/2552/001	53202	ORIFARM GENERICS A/S	SE
Acitretin Orifarm 10 mg kapseli, kova	DK/H/2552/001	33560	ORIFARM GENERICS A/S	FI
Acitretin Orifarm 25 mg kapseli, kova	DK/H/2552/002	33561	ORIFARM GENERICS A/S	FI
Keracutan 10 mg Kapseln	not available	1-31432	PELPHARMA HANDELS GMBH	AT
Keracutan 25 mg Kapseln	not available	1-31433	PELPHARMA HANDELS GMBH	AT
SORIATANE 10 mg, gélule	not available	NL 15451	ARROW GENERIQUES	FR
SORIATANE 25 mg, gélule	not available	NL : 15452	ARROW GENERIQUES	FR
NEOTIGASON 10 MG KIETOSIOS KAPSULĖS	not available	LT/1/94/0419/001	ACTAVIS GROUP PTC EHF.	LT
Neotigason 10mg Capsules	not available	PL 30306/0096	ACTAVIS GROUP PTC EHF.	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
Neotigason 25mg Capsules	not available	PL 30306/0097	ACTAVIS GROUP PTC EHF.	UK
Neotigason 10 mg kapseli, kova	not available	10116	ACTAVIS GROUP PTC EHF.	FI
Neotigason 25 mg kapseli, kova	not available	10117	ACTAVIS GROUP PTC EHF.	FI
Neotigason®	not available	60863/12/11-11-2013	ACTAVIS GROUP PTC EHF.	GR
Zorias 10 mg capsule	NL/H/1961/001	041619014	DIFA COOPER S.P.A.	IT
Zorias 10 mg capsule	NL/H/1961/001	041619026	DIFA COOPER S.P.A.	IT
Zorias 10 mg capsule	NL/H/1961/001	041619053	DIFA COOPER S.P.A.	IT
Zorias 25 mg capsule	NL/H/1961/002	041619038	DIFA COOPER S.P.A.	IT
Zorias 25 mg capsule	NL/H/1961/002	041619040	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
Zorias 25 mg capsule	NL/H/1961/002	041619065	DIFA COOPER S.P.A.	IT
Acitretina IFC 10 mg cápsulas duras EFG	NL/H/1961/001	74.727	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Acitretina IFC 25 mg cápsulas duras EFG	NL/H/1961/002	74.726	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Acitretine IFC 10 mg capsules	NL/H/1961/001	RVG 107057	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	NL
Acitretine IFC 25 mg capsules	NL/H/1961/002	RVG 107058	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	NL
Neotigason 10 mg kővakapszid	not available	083694	ACTAVIS GROUP PTC EHF.	EE
Neotigason, 10 mg, kapszki	not available	R/6970	ACTAVIS GROUP PTC EHF.	PL
Neotigason, 25 mg, kapszki	not available	R/6969	ACTAVIS GROUP PTC EHF.	PL
Neotigason 10mg capsules	not available	MA628/04101	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
Neotigason 25mg capsules	not available	MA628/04102	ACTAVIS GROUP PTC EHF.	MT
Neotigason 10 mg Tvrdé tobolky	not available	46/145/95-A/C	ACTAVIS GROUP PTC EHF.	CZ
Neotigason 25 mg Tvrdé tobolky	not available	46/145/95-B/C	ACTAVIS GROUP PTC EHF.	CZ
Neotigason 10 mg hörð hylki	not available	870227	ACTAVIS GROUP PTC EHF.	IS
Neotigason 25 mg hörð hylki.	not available	870226	ACTAVIS GROUP PTC EHF.	IS
Neotigason 10	not available	22414.00.00	PUREN PHARMA GMBH & CO. KG	DE
Neotigason 25	not available	22414.01.00	PUREN PHARMA GMBH & CO. KG	DE
Neotigason 10 mg capsules	not available	PA 1380/050/001	ACTAVIS GROUP PTC EHF.	IE
Neotigason 25 mg capsules	not available	PA 1380/050/002	ACTAVIS GROUP PTC EHF.	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
Neotigason 10 mg capsule rigide	not available	027480019	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
Neotigason 25 mg capsule rigide	not available	027480021	AUROBINDO PHARMA (ITALIA) S.R.L.	IT
NEOTIGASON 10 mg cietās kapsulas	not available	96-0595	ACTAVIS GROUP PTC EHF.	LV
Neotigason 10 mg hårda kapslar	not available	12742	ACTAVIS GROUP PTC EHF.	SE
Neotigason 25 mg hårda kapslar	not available	12743	ACTAVIS GROUP PTC EHF.	SE
Neotigason 10 mg kapsler, harde	not available	7759	ACTAVIS GROUP PTC EHF.	NO
Neotigason 25 mg kapsler, harde	not available	7760	ACTAVIS GROUP PTC EHF.	NO