



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 June 2017
EMA/372643/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: acitretin

Procedure no.: PSUSA/00000051/201610



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 kővakapslid	not available	083694	ACTAVIS GROUP PTC EHF.	EE
Neotigason 10mg hörð hylki	not available	870227	ACTAVIS GROUP PTC EHF.	IS
Neotigason 25mg hörð hylki	not available	870226	ACTAVIS GROUP PTC EHF.	IS
Neotigason 10 mg Kapseln	not available	1-18708	ACTAVIS GROUP PTC EHF.	AT
Neotigason 25 mg Kapseln	not available	1-18709	ACTAVIS GROUP PTC EHF.	AT
Neotigason 10mg Capsules	not available	PL 30306/0096	ACTAVIS GROUP PTC EHF.	UK
Neotigason 25mg Capsules	not available	PL 30306/0097	ACTAVIS GROUP PTC EHF.	UK
NEOTIGASON®	not available	60863/12/11-11-2013	ACTAVIS GROUP PTC EHF.	GR
NEOTIGASON®	not available	85248/11-11-2013	ACTAVIS GROUP PTC EHF.	GR
SORIATANE 10 mg, gélule	not available	15451	ARROW GENERIQUES	FR
SORIATANE 25 mg, gélule	not available	15452	ARROW GENERIQUES	FR
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 cápsulas duras	not available	60303	AUROVITAS SPAIN,S.A.U.	ES
Neotigason 25 mg cápsulas duras	not available	60302	AUROVITAS SPAIN,S.A.U.	ES
Neotigason 10 mg Cápsulas	not available	8756403	AUROVITAS UNIPessoal, LDA.	PT
Neotigason 10 mg Cápsulas	not available	8756411	AUROVITAS UNIPessoal, LDA.	PT
Neotigason 25 mg Cápsulas	not available	8756437	AUROVITAS UNIPessoal, LDA.	PT
Neotigason 25 mg Cápsulas	not available	8756429	AUROVITAS UNIPessoal, LDA.	PT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Neotigason 10 mg kapsule	not available	UP/I-530-09/11-02/243	ACTAVIS GROUP PTC EHF.	HR
Neotigason 25 mg kapsule	not available	UP/I-530-09/11-02/244	ACTAVIS GROUP PTC EHF.	HR
Neotigason 10 mg kapsule	not available	UP/I-530-09/11-02/243	ACTAVIS GROUP PTC EHF.	HR
Neotigason 25 mg kapsule	not available	UP/I-530-09/11-02/244	ACTAVIS GROUP PTC EHF.	HR
Neotigason®	not available	S00096	ACTAVIS GROUP PTC EHF.	CY
Neotigason®	not available	S00097	ACTAVIS GROUP PTC EHF.	CY
НЕОТИГАЗОН 10 МГ ТВЪРДИ КАПСУЛИ	not available	20010476	ACTAVIS GROUP PTC EHF.	BG
НЕОТИГАЗОН 25 МГ ТВЪРДИ КАПСУЛИ	not available	20010477	ACTAVIS GROUP PTC EHF.	BG
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 capsule	not available	4429/2004/01	ACTAVIS GROUP PTC EHF.	RO
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 10MG	not available	46/0661/95-S	ACTAVIS GROUP PTC EHF.	SK
NEOTIGASON 25MG	not available	46/0661/95-S	ACTAVIS GROUP PTC EHF.	SK
NEOTIGASON, 10 MG, KAPSUŁKI	not available	R/6970	ACTAVIS GROUP PTC EHF.	PL
NEOTIGASON, 25 MG, KAPSUŁKI	not available	R/6969	ACTAVIS GROUP PTC EHF.	PL
SORIATANE 10 mg, gélule	not available	15451	ARROW GENERIQUES	FR
SORIATANE 25 mg, gélule	not available	15452	ARROW GENERIQUES	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
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
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 KIETOSIOS KAPSULĖS	not available	LT/1/94/0419/001	ACTAVIS GROUP PTC EHF.	LT
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 10 mg cápsulas duras	not available	60303	AUROVITAS SPAIN,S.A.U.	ES
Neotigason 25 mg cápsulas duras	not available	60302	AUROVITAS SPAIN,S.A.U.	ES
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
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
Acitretine CF 10 mg, capsules	NL/H/1959/001	RVG 107065	CENTRAFARM B.V.	NL

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
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
Neotigason, hårde kapsler	not available	13124	ACTAVIS GROUP PTC EHF.	DK
Neotigason	not available	13125	ACTAVIS GROUP PTC EHF.	DK
NEOTIGASON®10 mg trde kapsule	not available	5363-I-2597/10	ACTAVIS GROUP PTC EHF.	SI
NEOTIGASON®25 mg trde kapsule	not available	5363-I-2598/10	ACTAVIS GROUP PTC EHF.	SI
Acicutan 10 mg Hartkapseln	NL/H/1958/001	81208.00.00	DERMAPHARM AG	DE
Acicutan 25 mg Hartkapseln	NL/H/1958/002	81209.00.00	DERMAPHARM AG	DE
Acitren 10 mg kapsulki	NL/H/1958/001/DC	18728	SUN-FARM SP. Z.O.O.	PL
Acitren 25 mg kapsulki	NL/H/1958/002/DC	18729	SUN-FARM SP. Z.O.O.	PL
Keraderm 10 mg capsules	NL/H/1958/001	RVG 107061	DERMAPHARM AG	NL
Keraderm 25 mg capsules	NL/H/1958/002	RVG 107062	DERMAPHARM AG	NL
Keracutan 10 mg Kapseln	not available	1-31432	PELPHARMA HANDELS GMBH	AT
Keracutan 25 mg Kapseln	not available	1-31433	PELPHARMA HANDELS GMBH	AT
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
Regioderm 10 mg capsule	NL/H/1960/001	042668018	REGIOMEDICA GMBH	IT

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Regioderm 10 mg capsules	NL/H/1960/001	RVG 107059	REGIOMEDICA GMBH	NL
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 capsules, hard	not available	BE144602	AUROBINDO PHARMA B.V.	BE
Neotigason 10 mg capsules, hard	not available	BE144706	AUROBINDO PHARMA B.V.	BE
Neotigason 25 mg Hartkapseln	not available	BE144602	AUROBINDO PHARMA B.V.	BE
Neotigason 10 mg gélules	not available	BE144706	AUROBINDO PHARMA B.V.	BE
Neotigason 10 mg Hartkapseln	not available	BE144706	AUROBINDO PHARMA B.V.	BE
Neotigason 25 mg gélules	not available	BE144602	AUROBINDO PHARMA B.V.	BE
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 cietās kapsulas	not available	96-0595	ACTAVIS GROUP PTC EHF.	LV
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
Neotigason	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