



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 June 2016  
EMA/540462/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: acitretin

Procedure no.: PSUSA/00000051/201510



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		027480019 \$ 027480021	Aurobindo Pharma (Italia) S.R.L.	Italy
Neotigason		60.302 \$ 60.303	Aurovitas Spain,s.A.U.	Spain
Neotigason		8756403 \$ 8756411 \$ 8756437	Aurovitas Unipessoal, Lda.	Portugal
Neotigason		RVG 13103 \$ RVG 13104	Aurobindo Pharma B.V.	Netherlands
Neotigason 10 Mg	NAT/H/3089/001-002	BE144706	Aurobindo Pharma B.V.	Belgium
Neotigason 25 Mg	NAT/H/3089/001-002	BE144602	Aurobindo Pharma B.V.	Belgium
Soriatane		15451 \$ 15452	Arrow Generiques	France
Neotigason		1.18708	Actavis Group PTC ehf.	Austria
Neotigason		1.18709	Actavis Group PTC ehf.	Austria
Neotigason		20010476	Actavis Group PTC ehf.	Bulgaria
Neotigason		20010477	Actavis Group PTC ehf.	Bulgaria
Neotigason		UP/I.530.09/11.02/243	Agmar d.o.o	Croatia
Neotigason		UP/I.530.09/11.02/244	Agmar d.o.o	Croatia
Neotigason		46/145/95.A/C	Actavis Group PTC ehf.	Czech Republic
Neotigason		46/145/95.B/C	Actavis Group PTC ehf.	Czech Republic
Neotigason		13124	Actavis Group PTC ehf.	Denmark
Neotigason		13125	Actavis Group PTC ehf.	Denmark
Neotigason		83694	Actavis Group PTC ehf.	Estonia
Neotigason		10116	Actavis Group PTC ehf.	Finland

Neotigason		10117	Actavis Group PTC ehf.	Finland
Neotigason		22414.00.00	Actavis Group PTC ehf.	Germany
Neotigason		22414.01.00	Actavis Group PTC ehf.	Germany
Neotigason		60863/12/11.11.2013	Actavis Group PTC ehf.	Greece
Neotigason		85248/11.11.2013	Actavis Group PTC ehf.	Greece
Neotigason		OGYI.T.4469/01	Actavis Group PTC ehf.	Hungary
Neotigason		OGYI.T.4469/02	Actavis Group PTC ehf.	Hungary
Neotigason		870227	Actavis Group PTC ehf.	Iceland
Neotigason		870226	Actavis Group PTC ehf.	Iceland
Neotigason		PA 1380/50/1	Actavis Group PTC ehf.	Ireland
Neotigason		PA 1380/50/2	Actavis Group PTC ehf.	Ireland
Neotigason		96.0595	Actavis Group PTC ehf.	Latvia
Neotigason		LT/1/94/0419/001	Actavis Group PTC ehf.	Lithuania
Neotigason		MA628/04101	Actavis Group PTC ehf.	Malta
Neotigason		MA628/04102	Actavis Group PTC ehf.	Malta
Neotigason		7759	Actavis Group PTC ehf.	Norway
Neotigason		7760	Actavis Group PTC ehf.	Norway
Neotigason		R/6970	Actavis Group PTC ehf.	Poland
Neotigason		R/6969	Actavis Group PTC ehf.	Poland

Neotigason		4429/2004/01	Actavis Group PTC ehf.	Romania
Neotigason		46/0661/95.S, 46/0263/15.S	Actavis Group PTC ehf.	Slovakia
Neotigason		H/96/01103/001	Actavis Group PTC ehf.	Slovenia
Neotigason		H/96/01103/002	Actavis Group PTC ehf.	Slovenia
Neotigason		12742	Actavis Group PTC ehf.	Sweden
Neotigason		72743	Actavis Group PTC ehf.	Sweden
Neotigason		30306/0096	Actavis Group PTC ehf.	UK
Neotigason		30306/0097	Actavis Group PTC ehf.	UK
Neotigason		S00096	Actavis Group PTC ehf.	Cyprus
Neotigason		S00097	Actavis Group PTC ehf.	Cyprus
Neotigason		BE 144602, BE 144706	Aurobindo Pharma B.V.	Netherlands