



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

Amsterdam, 10 June 2022  
Pharmacovigilance Risk Assessment Committee  
PSUSA/00000051/202110

## List of nationally authorised medicinal products

Active substance(s): acitretin

Procedure No. PSUSA/00000051/202110



| <b>Product Name (in authorisation country)</b> | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Acicutan 10 mg Hartkapseln                     | DE/H/5797/001                       | 81208.00.00                          | DERMAPHARM AG                             | DE                                              |
| Acicutan 25 mg Hartkapseln                     | DE/H/5797/002                       | 81209.00.00                          | DERMAPHARM AG                             | DE                                              |
| Acitren, 10 mg, kapsuľki twarde                | DE/H/5797/001                       | 18728                                | SUN-FARM SP. Z.O.O.                       | PL                                              |
| Acitren, 25 mg, kapsuľki twarde                | DE/H/5797/002                       | 18729                                | SUN-FARM SP. Z.O.O.                       | PL                                              |
| 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 10 mg Capsules                       | NL/H/1959/001                       | PL 06831/0251                        | GENUS PHARMACEUTICALS LIMITED             | XI                                              |
| Acitretin 10mg Capsules                        | not available                       | PL 20117/0265                        | MORNINGSIDE HEALTHCARE LTD                | XI                                              |
| Acitretin 25 mg Capsules                       | NL/H/1959/002                       | PL 06831/0252                        | GENUS PHARMACEUTICALS LIMITED             | XI                                              |
| Acitretin 25mg Capsules                        | not available                       | PL 20117/0266                        | MORNINGSIDE HEALTHCARE LTD                | XI                                              |
| 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 10 mg kapsler, harde         | DK/H/2552/001                       | 15-10784                             | ORIFARM GENERICS A/S                      | NO                                              |
| Acitretin Orifarm 25 mg hårda kapslar          | DK/H/2552/002                       | 53203                                | ORIFARM GENERICS A/S                      | SE                                              |
| Acitretin Orifarm 25 mg kapseli, kova          | DK/H/2552/002                       | 33561                                | ORIFARM GENERICS A/S                      | FI                                              |
| Acitretin Orifarm 25 mg kapsler, harde         | DK/H/2552/002                       | 15-10785                             | ORIFARM GENERICS A/S                      | NO                                              |
| 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 CF 10 mg, capsules                  | NL/H/1959/001                       | RVG 107065                           | CENTRAFARM B.V.                           | NL                                              |
| Acitretine CF 25 mg, capsules                  | NL/H/1959/002                       | RVG 107066                           | CENTRAFARM B.V.                           | NL                                              |
| 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                                              |
| Keracutan 10 mg Kapseln                        | not available                       | 1-31432                              | PELPHARMA HANDELS GMBH                    | AT                                              |
| Keracutan 25 mg Kapseln                        | not available                       | 1-31433                              | PELPHARMA HANDELS GMBH                    | 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 10                           | not available                | 22414.00.00                   | PUREN PHARMA GMBH & CO. KG         | DE                                       |
| Neotigason 10                           | not available                | 22414.00.00                   | PUREN PHARMA GMBH & CO. KG         | DE                                       |
| Neotigason 10 mg Cápsulas               | not available                | 8756403                       | GENERIS FARMACÉUTICA, S.A.         | PT                                       |
| Neotigason 10 mg Cápsulas               | not available                | 8756411                       | GENERIS FARMACÉUTICA, S.A.         | PT                                       |
| Neotigason 10 mg cápsulas duras         | not available                | 60.303                        | AUROVITAS SPAIN,S.A.U.             | ES                                       |
| Neotigason 10 mg capsule rigide         | not available                | 027480019                     | AUROBINDO PHARMA (ITALIA) S.R.L.   | IT                                       |
| Neotigason 10 mg capsules               | not available                | PA 1380/050/001               | ACTAVIS GROUP PTC EHF.             | IE                                       |
| NEOTIGASON 10 mg cietās kapsulas        | not available                | 96-0595                       | ACTAVIS GROUP PTC EHF.             | LV                                       |
| Neotigason 10 mg gélules                | not available                | BE144706                      | AUROBINDO N.V.                     | BE                                       |
| Neotigason 10 mg gélules                | not available                | 2003107909                    | AUROBINDO N.V.                     | LU                                       |
| Neotigason 10 mg hårda kapslar          | not available                | 10116                         | ACTAVIS GROUP PTC EHF.             | FI                                       |
| Neotigason 10 mg hårda kapslar          | not available                | 12742                         | ACTAVIS GROUP PTC EHF.             | SE                                       |
| Neotigason 10 mg harde capsules         | PT-H-3049                    | BE144706                      | AUROBINDO N.V.                     | BE                                       |
| Neotigason 10 mg Hartkapseln            | not available                | BE144706                      | AUROBINDO N.V.                     | BE                                       |
| Neotigason 10 mg Hartkapseln            | not available                | 2003107909                    | AUROBINDO N.V.                     | LU                                       |
| Neotigason 10 mg kapseli, kova          | not available                | 10116                         | ACTAVIS GROUP PTC EHF.             | FI                                       |
| Neotigason 10 mg kapsler, harde         | not available                | 7759                          | ACTAVIS GROUP PTC EHF.             | NO                                       |
| Neotigason 10 mg kemény kapszula        | not available                | OGYI-T-4469/01                | ACTAVIS GROUP PTC EHF.             | HU                                       |
| NEOTIGASON 10 MG KIETOSIOS KAPSULĖS     | not available                | LT/1/94/0419/001              | ACTAVIS GROUP PTC EHF.             | LT                                       |
| Neotigason 10 mg kõvakapslid            | not available                | 083694                        | ACTAVIS GROUP PTC EHF.             | EE                                       |
| NEOTIGASON 10 mg trde kapsule           | not available                | H/96/01103/001                | ACTAVIS GROUP PTC EHF.             | SI                                       |
| Neotigason 10 mg tvrde kapsule          | not available                | HR-H-047281874                | ACTAVIS GROUP PTC EHF.             | HR                                       |
| Neotigason 10 mg Tvrdé tobolky          | not available                | 46/145/95-A/C                 | ACTAVIS GROUP PTC EHF.             | CZ                                       |
| Neotigason 10 mg, capsules              | not available                | RVG 13103                     | AUROBINDO PHARMA B.V.              | NL                                       |
| NEOTIGASON 10MG                         | not available                | 46/0661/95-S                  | ACTAVIS GROUP PTC EHF.             | SK                                       |
| Neotigason 10mg Capsules                | not available                | PL 30306/0096                 | ACTAVIS GROUP PTC EHF.             | XI                                       |
| Neotigason 10mg hörð hylki              | not available                | 870227                        | ACTAVIS GROUP PTC EHF.             | IS                                       |
| Neotigason 25                           | not available                | 22414.01.00                   | PUREN PHARMA GMBH & CO. KG         | DE                                       |
| Neotigason 25                           | not available                | 22414.01.00                   | PUREN PHARMA GMBH & CO. KG         | DE                                       |
| Neotigason 25 mg Cápsulas               | not available                | 8756437                       | GENERIS FARMACÉUTICA, S.A.         | PT                                       |
| Neotigason 25 mg Cápsulas               | not available                | 8756429                       | GENERIS FARMACÉUTICA, S.A.         | PT                                       |
| Neotigason 25 mg cápsulas duras         | not available                | 60.302                        | AUROVITAS SPAIN,S.A.U.             | ES                                       |
| Neotigason 25 mg capsule rigide         | not available                | 027480021                     | AUROBINDO PHARMA (ITALIA)          | IT                                       |

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|                                         |                              |                               | S.R.L.                             |                                          |
| Neotigason 25 mg capsules               | not available                | PA 1380/050/002               | ACTAVIS GROUP PTC EHF.             | IE                                       |
| Neotigason 25 mg gélules                | not available                | BE144602                      | AUROBINDO N.V.                     | BE                                       |
| Neotigason 25 mg gélules                | not available                | 2003107910                    | AUROBINDO N.V.                     | LU                                       |
| Neotigason 25 mg hårda kapslar          | not available                | 10117                         | ACTAVIS GROUP PTC EHF.             | FI                                       |
| Neotigason 25 mg hårda kapslar          | not available                | 12743                         | ACTAVIS GROUP PTC EHF.             | SE                                       |
| Neotigason 25 mg harde capsules         | PT-H-3049                    | BE144602                      | AUROBINDO N.V.                     | BE                                       |
| Neotigason 25 mg Hartkapseln            | not available                | BE144602                      | AUROBINDO N.V.                     | BE                                       |
| Neotigason 25 mg Hartkapseln            | not available                | 2003107910                    | AUROBINDO N.V.                     | LU                                       |
| Neotigason 25 mg kapseli, kova          | not available                | 10117                         | ACTAVIS GROUP PTC EHF.             | FI                                       |
| Neotigason 25 mg kapsler, harde         | not available                | 7760                          | ACTAVIS GROUP PTC EHF.             | NO                                       |
| Neotigason 25 mg kemény kapszula        | not available                | OGYI-T-4469/02                | ACTAVIS GROUP PTC EHF.             | HU                                       |
| Neotigason 25 mg tvrde kapsule          | not available                | HR-H-770001325                | ACTAVIS GROUP PTC EHF.             | HR                                       |
| Neotigason 25 mg Tvrde tobolky          | not available                | 46/145/95-B/C                 | ACTAVIS GROUP PTC EHF.             | CZ                                       |
| Neotigason 25 mg, capsules              | not available                | RVG 13104                     | AUROBINDO PHARMA B.V.              | NL                                       |
| Neotigason 25mg Capsules                | not available                | PL 30306/0097                 | ACTAVIS GROUP PTC EHF.             | XI                                       |
| Neotigason 25mg hörð hylki              | not available                | 870226                        | ACTAVIS GROUP PTC EHF.             | IS                                       |
| NEOTIGASON 25MG tvrde kapsuly           | not available                | 46/0263/15-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                                       |
| Neotigason, hårde kapsler               | not available                | 13124                         | ACTAVIS GROUP PTC EHF.             | DK                                       |
| Neotigason, hårde kapsler               | not available                | 13125                         | ACTAVIS GROUP PTC EHF.             | DK                                       |
| NEOTIGASON®25 mg trde kapsule           | not available                | H/96/01103/002                | ACTAVIS GROUP PTC EHF.             | SI                                       |
| SORIATANE 10 mg, gélule                 | not available                | NL 15451                      | ARROW GENERIQUES                   | FR                                       |
| SORIATANE 25 mg, gélule                 | not available                | NL 15452                      | ARROW GENERIQUES                   | FR                                       |
| 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                                       |