Summary of Product Characteristics

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See SmPC section 4.8 of PA1380/050/002 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

Neotigason 25 mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 25 mg acitretin.

Excipient with known effect
Glucose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule

Product imported from Spain
Capsules with brown cap and yellow body with '25' printed in black on the body.

4 CLINICAL PARTICULARS

As per PA1380/050/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1380/050/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents
Glucose
Sodium ascorbate (E301)
Cellulose, microcrystalline (E460i)
Gelatin

Capsule shell
Iron oxide black (E172)
Iron oxide yellow (E172)
Iron oxide red (E172)
Titanium dioxide (E171)
Gelatin

Printing ink
Shellac
Propylene glycol
Isopropyl alcohol
n-butyl alcohol
Ammonium hydroxide
Iron oxide black (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blisters of 60 capsules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 MARKETING AUTHORISATION NUMBER

PPA2306/020/001

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th November 2019

10 DATE OF REVISION OF THE TEXT