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 PA1986/113/001 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

Neotigason 10 mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 10 mg of 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
Capsule with a brown cap and white body with '10' printed in black on the body.

4 CLINICAL PARTICULARS

As per PA1986/113/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1986/113/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:
Glucose
Sodium ascorbate (E 301)
Gelatin
Microcrystalline cellulose (E 460i)

Capsule shell:
Gelatin
Iron oxide black (E 172)
Iron oxide yellow (E 172)
Iron oxide red (E 172)
Titanium dioxide (E 171)

Printing ink:
Shellac
Isopropyl alcohol
n-Butyl alcohol
Propylene glycol
Ammonium hydroxide

Iron oxide black (E 172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister and outer package of the product as marketed 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 containing 60 hard capsules.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/480/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th February 2022

10 DATE OF REVISION OF THE TEXT

September 2022