

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 PA1986/113/002 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 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

Capsules with a brown cap and yellow body with '25' printed in black on the body.

4 CLINICAL PARTICULARS

As per PA1986/113/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1986/113/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:

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

Capsule shell:

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

Printing ink:

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of 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 in cardboard carton containing 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/480/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th November 2021

10 DATE OF REVISION OF THE TEXT

September 2022