

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neotigason 10 mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Capsules containing 10 mg of acitretin.

Excipients with known effect: glucose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

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)
Microcrystalline cellulose (E-460i)
Gelatin

Capsule shell:

Black iron oxide (E-172)
Yellow iron oxide (E-172)
Red iron oxide (E-172)
Titanium dioxide (E-171)
Gelatin

Printing ink:

Shellac
Isopropyl alcohol
N-butyl alcohol
Propylene glycol
Ammonium hydroxide
Black iron oxide (E-172)

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 to protect from moisture.

6.5 Nature and contents of container

Blisters of 60 capsules in an outer carton.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/238/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th July 2025

10 DATE OF REVISION OF THE TEXT