

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neotigason 10mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Capsules containing 10 mg of acitretin.
Excipient with known effect: Glucose

For the full list of excipients, *see section 6.1*

3 PHARMACEUTICAL FORM

Capsule, hard.

Product imported from Greece

Capsule with a brown cap and white body with 'Actavis' printed in black on the cap and '10' printed in black on the body; capsule size 4.

4 CLINICAL PARTICULARS

As per PA1380/050/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1380/050/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:

Gelatin
Glucose, liquid, spray-dried
Sodium ascorbate
Cellulose Microcrystalline

Capsule shell:

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

Printing ink:

Shellac
Isopropyl alcohol
N-butyl alcohol
Propylene glycol
Ammonium hydroxide
Gelatin

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

Blister: Aluminium cover foil containing 60 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th April 2018

10 DATE OF REVISION OF THE TEXT