

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 section 4.8 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

Roaccutane 20 mg soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains 20 mg of isotretinoin.

Excipients with known effect:

Contains soya-bean oil (refined, hydrogenated and partially hydrogenated) and sorbitol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Soft capsules

Product imported from Belgium:

Oval, opaque, brown-red and white capsules imprinted with ROA 20 in black ink.

4 CLINICAL PARTICULARS

As per PA2307/007/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2307/007/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Beeswax, yellow

Soya-bean oil, refined

Soya-bean oil, hydrogenated

Soya-bean oil, partially hydrogenated

Gelatin

Glycerol 85 %

Sorbitol (E 420)

Mannitol

Hydrogenated hydrolysed starch

Titanium dioxide (E 171)

Red iron oxide (E 172)

Dry printing ink:

Shellac, modified

Black iron oxide (E 172)

Propylene glycol (E 1520)

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 carton 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 and keep blister in the outer carton in order to protect from moisture and light.

6.5 Nature and contents of container

Aluminium blister pack containing 30 capsules.

6.6 Special precautions for disposal

Return any unused Roaccutane capsules to the Pharmacist.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/493/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th August 2022

10 DATE OF REVISION OF THE TEXT