

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Roaccutane 20 mg soft capsules.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains 20 mg isotretinoin

Excipients with known effect:

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules, soft

Product imported from Slovakia

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

4 CLINICAL PARTICULARS

As per PA0050/053/004

5 PHARMACOLOGICAL PROPERTIES

As per PA0050/053/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule filling:

Beeswax, yellow;

Soya-bean oil, refined;

Soya-bean oil, hydrogenated;

Soya-bean oil, partially hydrogenated.

Capsule shell:

Gelatin;

Glycerol

Sorbitol, mannitol, hydrogenated hydrolysed starch;

Titanium dioxide (E171);

Red iron oxide (E172).

Dry printing ink:

Shellac,

Black iron oxide (E172);

Propylene Glycol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer package of the product 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

Blister packs containing 30 capsules

6.6 Special precautions for disposal

Return any unused Roaccutane capsules to the Pharmacist.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/105/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 2016

10 DATE OF REVISION OF THE TEXT