

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Creon 25000 Gastro-resistant capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 300 mg Pancreatin equivalent to:

Lipase 25,000 Ph. Eur. units

Amylase 18,000 Ph. Eur. units

Protease 1,000 Ph. Eur. Units

Produced from porcine pancreatic tissue.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant capsule, hard.

Product imported from Poland and Czech Republic:

Hard gelatin capsules with opaque brick-red caps and colourless transparent bodies filled with gastro-resistant brown granules.

4 CLINICAL PARTICULARS

As per PA2010/008/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/008/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Granules:

Macrogol 4000

Hypromellose Phthalate

Cetyl alcohol

Triethyl citrate

Dimethicone

Capsules:

Gelatin

Red and Yellow Iron Oxides (E172)

Titanium dioxide (E171)

Sodium lauryl sulphate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

After first opening: 6 months

The shelf-life expiry date of this product is the date shown on the container and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Plastic container containing 50 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/033/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th January 2013

10 DATE OF REVISION OF THE TEXT

May 2021