

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Creon 25000 Gastro-resistant Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 300mg 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 the United Kingdom:

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

4 CLINICAL PARTICULARS

As per PA2007/003/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2007/003/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Granules:

Macrogol 4000
Hypromellose Phthalate
Cetyl alcohol
Triethyl citrate
Dimethicone

Capsules:

Gelatin
Iron Oxides (E172)
Titanium dioxide (E171)
Sodium lauryl sulphate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister strips and outer carton of the product as marked in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

White container in a cardboard outer carton.

Pack size: 100 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

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/065/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th June 2014

10 DATE OF REVISION OF THE TEXT

June 2015