

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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant capsule, hard.

Product imported from Greece, Hungary and Poland:

Hard gelatin capsules with opaque brick-red 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

Macrogol 4000

Hypromellose phthalate

Cetyl alcohol

Triethyl citrate

Dimethicone

Gelatin

Red, yellow and black 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 container and outer package of the product on the market in the country of origin.

After first opening: use within 6 months

6.4 Special precautions for storage

Do not store above 25 °C.
Keep in the original container and keep it tightly closed.

6.5 Nature and contents of container

Plastic bottle with plastic closure.
Pack size: 50 capsules

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/125/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th June 2004

Date of last renewal : 24th June 2009

10 DATE OF REVISION OF THE TEXT

February 2021