

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Creon 10000 Gastro-resistant Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 150 mg pancreatin, equivalent to:

Lipase 10,000 Ph.Eur. units
Amylase 8,000 Ph.Eur. units
Protease 600 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, The Czech Republic, Hungary and Italy:

Hard gelatin capsules with brown caps and colourless bodies filled with gastro-resistant brown granules.

4 CLINICAL PARTICULARS

As per PA2010/008/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/008/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 4000
Hypromellose phthalate
Dimethicone
Cetyl alcohol
Triethyl citrate
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 the container tightly closed.

6.5 Nature and contents of container

Plastic bottle with plastic closure.
Pack size: 50 or 100 capsules

Not all pack sizes may be marketed.

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

PPA0465/125/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th June 2004

10 DATE OF REVISION OF THE TEXT

February 2021