

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 a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant capsule, hard

Product imported from Italy:

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

4 CLINICAL PARTICULARS

As per [PA23355/006/001](#)

5 PHARMACOLOGICAL PROPERTIES

As per [PA23355/006/001](#)

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 4000
Hypromellose phthalate
Triethyl citrate
Cetyl alcohol
Dimethicone

Capsule shell:

Gelatin
Red, yellow and black iron oxides (E172)
Titanium dioxide (E171)
Sodium laurilsulfate

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: 6 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Plastic container of 100 capsules or 2 plastic containers (2 x 50 capsules) in a cardboard carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/145/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd February 2008

10 DATE OF REVISION OF THE TEXT

September 2023