

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 capsules, hard.

Product imported from Czech Republic.

Size 0, hard gelatin capsules with opaque orange caps and colourless transparent bodies filled with gastro-resistant brown granules.

4 CLINICAL PARTICULARS

As per PA 2010/008/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA 2010/008/002.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Granules
Macrogol 4000
Hypromellose phthalate
Dimeticone 1000
Triethyl citrate
Cetyl alcohol

Capsules
Red and yellow iron oxide (E172)
Titanium dioxide (E171)
Sodium Lauril sulfate
Gelatin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the container and outer package 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.

6.5 Nature and contents of container

HDPE container with polypropylene closure, containing 50 capsules.

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18,
Oxleasow Road,
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Redditch,
Worcestershire B98 0RE,
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/143/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th February 2015.

10 DATE OF REVISION OF THE TEXT

October 2017