

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 the UK.

Capsules with brown caps and colourless, transparent bodies filled with gastro-resistant brownish granules (minimicrospheres).

4 CLINICAL PARTICULARS

As per PA2010/008/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/008/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Granules:

Macrogol4000

Hypromellosephthalate

Triethylcitrate

Cetylalcohol

Dimethicone.

Capsuleshell:

Gelatin,

Iron oxides(E172)

Titanium dioxide(E171)

Sodium laurylsulphate

6.2 Incompatibilities

Notapplicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

HDPE container with polypropylene cap. Containers hold 100 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
Unit C4 Metropoint Business Park
Kettles Lane
Swords
Co Dublin
K67 RH92
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/019/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th February 2018

10 DATE OF REVISION OF THE TEXT

May 2021