

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Creon 10000 Gastro-resistant Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Gastro-resistant capsule contains 150mg Pancreatin equivalent to:

Lipase 10,000 Ph. Eur. units
Amylase 8,000 Ph. Eur. units
Protease 600 Ph. Eur. units

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant capsule, hard

Product imported from the UK and Hungary:
Capsules with brown caps and colourless bodies filled with gastro-resistant brownish 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

Granules
Macrogol 4000
Hypromellose phthalate
Dimeticone
Cetyl alcohol
Triethyl citrate

Capsules
Gelatin
Iron oxides (E172)
Titanium dioxide (E171)
Sodium lauril sulfate

6.2 Incompatibilities

Not applicable.

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.

6.5 Nature and contents of container

HDPE over-labelled container with polypropylene cap. Containers hold 50 or 100 capsules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

PPA1463/033/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th February 2010

10 DATE OF REVISION OF THE TEXT

August 2017