

# 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 capsule, hard.

*Product imported from Czech Republic and Slovakia:*

Hard gelatin capsules with opaque brick-red caps and colourless transparent bodies filled with gastro-resistant brown granules.

## 4 CLINICAL PARTICULARS

As per PA23355/006/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23355/006/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Product as sourced from Czech Republic*

Granules:

Macrogol 4000

Hypromellose Phthalate

Cetyl alcohol

Triethyl citrate

Dimethicone

Capsules:

Gelatin

Red and Yellow Iron Oxides (E172)

Titanium dioxide (E171)

Sodium lauryl sulphate

*Product as sourced from Slovakia*

Granules:

Macrogol 4000

Hypromellose Phthalate

Cetyl alcohol

Triethyl citrate

Dimethicone

Capsules:  
Gelatin  
Red and Yellow Iron Oxides (E172)

Sodium lauryl sulphate

## **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 carton 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 the container tightly closed in order to protect from moisture.

## **6.5 Nature and contents of container**

Plastic container containing 50 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**

PPA1463/033/002

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 10<sup>th</sup> January 2013

## **10 DATE OF REVISION OF THE TEXT**

February 2024