Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Creon 10000 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

Capsule, hard
Product imported from Italy, Greece and Spain:
Size 2 hard gelatin capsules with brown caps and colourless bodies filled with gastro-resistant brown granules.

4 CLINICAL PARTICULARS

As per PA 2007/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 2007/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Granules:
Macrogol 4000
Hypromellose phthalate
Triethyl citrate
Cetyl alcohol
Dimeticone.

Capsule shell:
Gelatin,
Sodium lauryl sulphate
Red, yellow and black iron oxides (E172)
Titanium dioxide (E171).

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.

6.4 Special precautions for storage

Do not store above 30°C. Keep the container tightly closed.

6.5 Nature and contents of container

HDPE container with LDPE cap, containing 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

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/065/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 15th December 2006

Date of Last Renewal: 15th Decmeber 2011

10 DATE OF REVISION OF THE TEXT

November 2015