Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Creon 10000 Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

150 mg 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 capsules, hard.

Product imported from the UK and Hungary:
Hard gelatin capsules with brown caps and colourless bodies filled with gastro-resistant brown granules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Pancreatic exocrine deficiency.

4.2 Posology and method of administration

Adults (including the elderly) and children:

Initially one to two capsules with meals. Dose increases, if required, should be added slowly, with careful monitoring of response and symptomatology. The daily dose of pancreatic enzymes for most patients should remain below 2500 units of lipase per kilogram per meal (10,000 units per kilogram per day), and that higher doses should be used with caution and only if quantitative measures demonstrate substantially improved absorption with such treatment. This applies particularly to young children.

It is important to ensure adequate hydration of patients at all times whilst dosing Creon.

The capsules can be swallowed whole, or for ease of administration they may be opened and the granules taken with fluid or soft food. If the granules are mixed with food, it is important that they are taken immediately, otherwise dissolution of the enteric coating may result. In order to protect the enteric coating, it is important that the granules are not crushed or chewed *(see 4.8 Undesirable Effects).*

Colonic damage has been reported in patients with cystic fibrosis taking high doses of pancreatic enzyme supplements *(see 4.8 Undesirable effects).*

4.3 Contraindications

Use in patients with known hypersensitivity to porcine proteins.

4.4 Special warnings and precautions for use

The product is of porcine origin.

Oral medications should not be administered during the early stages of acute pancreatitis.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of Creon in pregnant women. Animal studies are insufficient with respect to effects on pregnancy and embryonal/foetal development, parturition/ and postnatal development. The potential risk for humans is unknown. Creon should not be used during pregnancy or lactation unless clearly necessary but if required should be used in doses providing adequate nutritional status *(see warnings about high dose sections 4.2 & 4.8.)*

4.7 Effects on ability to drive and use machines

None expected.

4.8 Undesirable effects

1. Rarely, cases of hyper-uricosuria and hyper-uricaemia have been reported with very high doses of pancreatin.

2. Meconium ileus type obstructive symptoms and cases of colonic stricture resulting in bowel re-section, have been seen with high doses of pancreatic enzyme supplements. Similar problems have not occurred to date with this product. However, unusual abdominal symptoms or changes in abdominal symptoms should be reviewed to exclude the possibility of colonic damage.

3. The following unwanted effects have been reported with Creon: diarrhoea, constipation, stomach pains, feeling sick, and skin reactions (rash, itching).

4.9 Overdose

Symptoms: Overdosage, although not experienced to date, could precipitate meconium ileus or other bowel obstructive symptoms.

Treatment: Most cases respond to supportive measures including stopping enzyme therapy, ensuring adequate rehydration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Replacement therapy in pancreatic enzyme deficiency states. The enzymes have hydrolytic activity on fat, carbohydrates and proteins.

5.2 Pharmacokinetic properties

Pharmacokinetic data are not available as the enzymes act locally in the gastro-intestinal tract. After exerting their action, the enzymes are digested themselves in the intestine.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Granules:

Macrogol 4000
Hypromellose phthalate
Triethyl citrate
Cetyl alcohol
Dimeticone

Capsule shell:

Gelatin
Red, yellow and black iron oxides (E172)
Titanium dioxide (E171)
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 as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30ºC.

6.5 Nature and contents of container

Over-labelled cardboard carton containing a white HDPE container with polypropylene cap.
Pack sizes: 50 capsules 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

Profind Wholesale Ltd
Unit 625, Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1500/81/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th May 2011

10 DATE OF REVISION OF THE TEXT