IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PPA1473/018/001
Case No: 2078963

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

McDowell Pharmaceuticals

4 Altona Road, **Lisburn**, **N. Ireland**, **BT27 5QB**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Creon 25000 300mg Gastro-Resistant Capsules

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **10/03/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Creon 25000 300mg Gastro-Resistant Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capusle contains 300mg pancreatin, equivalent to:

- Lipase 25,000 Ph. Eur. units
- Amylase 18,000 Ph. Eur. units
- Protease 1,000 Ph. Eur. units

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant capsule, hard

Product imported from the United Kingdom:
Hard gelatin capsules with opaque orange caps and colourless transparent bodies filled with gastro-resistant brown granules.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of pancreatic exocrine deficiency.

4.2 Posology and method of administration

Adults (including the elderly) and children:

Initially one capsule 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 particularly applies to young children.

It is important to ensure adequate hydration of patients at all times whilst dosing Creon 25000.

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.

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

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 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 and 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

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

Macrogol 4000
Hypromellose phthalate
Dimeticone
Cetyl alcohol
Triethyl citrate

Capsule shell:
Gelatin
Iron oxides (E172)
Titanium dioxide (E171)
Sodium laurilsulfate

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.

6.5 Nature and contents of container

Overlabelled HDPE container with polypropylene closure containing 100 capsules.

6.6 Special precautions for disposal and other handling

No special requirements

7 Parallel Product Authorisation Holder

Mc Dowell Pharmaceuticals
4 Altona Road
Lisburn
Northern Ireland
BT 27 5QB

8 Parallel Product Authorisation Number

PPA1473/18/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd May 2009

10 DATE OF REVISION OF THE TEXT

March 2010