

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Trade name : **Enzystal P**

Generic name : Pancreatin Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each enteric coated tablet contains:

Pancreas powder Ph. Eur. equivalent to

Amylase activity 4200 Ph. Eur. Units

Lipase activity 3500 Ph. Eur. units

Protease activity..... 250 Ph. Eur. units

Colours: Lake of Carmoisine and Titanium

dioxideExcipients q.s.

3. PHARMACEUTICAL FORM

Pink coloured, round, biconvex enteric coated tablet.

4. CLINICAL PARTICULAR

4.1 Therapeutic Indication

Pancreatin Tablets is used to compensate for reduced intestinal enzyme activity in pancreatic deficiency states.

It is indicated for the treatment of fibrocystic disease of the pancreas (cystic fibrosis), chronic pancreatitis and pancreatic steatorrhoea following pancreatectomy. It may also be indicated following gastrectomy as an aid to digestion

4.2 Posology and Method of Administration

Dosage should be adjusted according to the needs of the individual patient and the amount and type of food consumed.

The following dosage ranges provide a suitable basis for adjustment.

Adults, the Elderly, and Children

6 - 10 tablets before each snack or meal, swallowed whole.

4.3 Contraindications

Hypersensitivity to the active ingredient (porcine pancreatin) or any of the excipients.

4.4 Special warnings and precautions for use

Unsuitable for people with lactase insufficiency, galactosaemia or glucose/galactose malabsorption syndrome.

Variations in response to treatment may be due to enteric coating. It is possible that some

irritation of the skin of the mouth may occur if tablets are chewed or preparations retained in the mouth. Irritation of the anus may also occur. A barrier cream may prevent this local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pancreatin Tablets should not be used in pregnancy and lactation unless clearly necessary but if required should be used in doses sufficient to provide adequate nutritional status.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Rare cases of hyperuricosuria and hyperuricaemia have been reported when extremely high doses of pancreatin have been taken.

Strictures of the ileo-caecum and large bowel, and colitis, have been reported in children with cystic fibrosis taking high doses of pancreatic enzyme supplements. To date Pancreatin Tablets presentations have not been implicated in the development of colonic damage. However unusual abdominal symptoms or changes in abdominal symptoms should be reviewed to exclude the possibility of colonic damage especially if the patient is taking in excess of 10,000 units/kg/day of lipase.

4.9 Overdose

None stated.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pancreatin is derived from porcine pancreas and contains the enzymes, amylase, protease and lipase. The enzymes have the same action as pancreatic juice and when administered to patients with pancreatic insufficiency improve the ability to metabolise starches, proteins and fats.

5.2 Pharmacokinetic properties

Pancreatin hydrolyses fats to glycerol and fatty acids, changes proteins into proteases and derived substances, and converts starch into dextrins and sugars.

5.3 Preclinical safety data

No relevant pre-clinical safety data has been generated.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose monohydrate, microcrystalline cellulose (Avicel PH 101), magnesium stearate , colloidal silicon dioxide, sodium starch glycollate-(Type-A), talc, macrogol, Titanium dioxide, Isopropyl alcohol, methylene chloride, Cellulose acetate phthalate, Diethyl Phthalate, Acetone, Pregelatinized starch, Hypromellose 2910(6 cps), White Bees Wax, Lake of Carmosine

Important information about some of the ingredients of Enzystal P Tablets

The product is derived from porcine pancreas and contains lactose.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Enzystal P Tablets are packed in plain aluminium foil along with the cold form blister foil. The blisterstrips will be packed in cartons according to the approved pack size.

Proposed Pack Size: 10s

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorization

holderMANUFACTURED BY

M/s Torrent Pharmaceuticals
Ltd.Village: Bhud & Makhnu
Majra,
Tehsil: Baddi- 173 205,Distt: Solan [H.P.]

MARKETED BY

Torrent Pharmaceuticals
Ltd. "Torrent House"
Off Ashram Road,
Ahmedabad – 380 009,
India
Tel No.: +91-79-
26583060/26585090Fax. No.:
+91-79-26582100

8. Marketing authorization number

TAN 22 HM 0085

9. Date of renewal of the authorization

Not Applicable

10. Date of revision of the text

April, 2022