

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pancrex V 340 mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 340 mg pancreatin to provide enzymatic activity per capsule not less than:

Free protease	430 BP units
Lipase	8000 BP units
Amylase	9000 BP units

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule (capsule).

A white or buff coloured powder in ivory coloured opaque hard gelatin capsules imprinted Pancrex V and the company logo.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Pancrex V 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

Posology

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.

Infants: the contents of 1 - 2 capsules mixed with feeds.

Older Children and Adults: the contents of 2 - 6 capsules with each snack or meal.
The capsules may be swallowed.

The capsules may provide a suitable alternative to the enteric coated presentations in cases where the pH of the duodenum is not sufficiently alkaline to dissolve the enteric coat.

Paediatric population

Capsules provide a simple and convenient method of dose measurement of pancreatin for administration to younger children requiring a low dose.

Method of administration

Oral use.

The capsules should be taken with each feed or meal or snack.

If the capsule contents are mixed with liquids or feeds the resulting mixture should not be allowed to stand for more than one hour prior to use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

It is possible that some irritation of the skin of the mouth may occur if capsules are chewed or the contents retained in the mouth. Irritation of the anus may also occur. A barrier cream may prevent this local irritation.

Allergic/asthmatic reactions have occasionally occurred on handling the capsule contents.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pancrex V 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

Pancrex V has no or negligible influence on the ability to drive and use machines.

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 Pancrex and Pancrex V 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Digestives, incl. enzymes, enzyme preparations, ATC code: A09AA02.

Mechanism of action

Pancreatin is derived from porcine pancreas and contains the enzymes, amylase, protease and lipase. The enzymes have the same actions 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 dextrans and sugars.

5.3 Preclinical safety data

No relevant pre-clinical safety data has been generated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule shell

Gelatin

Titanium dioxide (E171)

Yellow iron oxide (E172)

Quinoline yellow (E104)

Capsule content

Aluminium oxide

Magnesium stearate

Microcrystalline cellulose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).

6.5 Nature and contents of container

The drug product is contained in a polypropylene securitainer with low density polyethylene cap.

Securitainer: 100, 300 and 500 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Essential Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 41094/0006

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

Date of first authorisation: 13/11/1985
Date of latest renewal: 31/05/2001

10 DATE OF REVISION OF THE TEXT

10/06/2022