SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pancrex V Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram powder contains pancreatin BP to provide enzymatic activity not less than:

Free protease 1400 BP units

Lipase 25000 BP units

Amylase 30000 BP units

Excipient(s) with known effect

Lactose monohydrate

3 PHARMACEUTICAL FORM

Oral powder.

A white or buff coloured amorphous powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Pancrex 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 dosing may also require to be adjusted, as necessary, on the basis of the clinical outcome. The following dosage ranges provide a suitable basis for adjustment.

Adults, the Elderly, and Paediatric population
0.5- 2 grams swallowed dry or mixed with a little water or milk before each snack or meal.

New-born infants
0.25 - 0.5 grams with each feed.

1 gram of Pancrex V Powder corresponds approximately to the volume of a 1.25 ml spoonful.
2 grams of Pancrex V Powder correspond approximately to the volume of a 2.5 ml spoonful.

Method of administration
(1) Oral use
(2) Pancrex V Powder may be administered via a nasogastric tube or a gastrostomy tube. Refer to relevant local and national official guidelines (see section 4.4).

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

Strictures of the ileo-caecum and large bowel (fibrosing colonopathy) have been reported in patients with cystic fibrosis taking high doses of pancreatin preparations. As a precaution, unusual abdominal symptoms or changes in abdominal symptoms should be medically assessed to exclude the possibility of fibrosing colonopathy, especially if the patient is taking in excess of 10,000 units of lipase/kg/day.

It is possible that some irritation of the skin of the mouth may occur if the powder is 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 powder.

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

When Pancrex V Powder is administered via a nasogastric tube or a gastrostomy tube then the internal diameter of the tube must be adequate and patency of the tube must be ensured. Refer to relevant local and national official guidelines.

Excipients
This medicine contains lactose monohydrate. Patients with rare hereditary problems of, galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of pancreatic enzymes in pregnant women. Animal studies show no evidence for any absorption of porcine pancreatic enzymes. Therefore, no reproductive or developmental toxicity is to be expected.
Pancrex V Powder should be used with caution in pregnancy.

Lactation
No effects on the breastfed newborn/infant are anticipated since animal studies suggest no systemic exposure of the breast-feeding woman to pancreatic enzymes.

If use during pregnancy and lactation is considered necessary, Pancrex V Powder should be used in doses sufficient to provide adequate nutritional status.

4.7 Effects on ability to drive and use machines

Pancrex V Powder 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.

The following adverse reactions have been observed during clinical trials with the below indicated frequencies:

Organ system	Very common ≥ 1/10	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100	Frequency not known (cannot be estimated from the available data)
Immune system disorders				hypersensitivity (anaphylactic reactions)
Gastrointestinal disorders	abdominal pain*	nausea, vomiting, constipation, abdominal distention, diarrhoea*		strictures of the ileo-caecum and large bowel (fibrosing colonopathy)
Skin and subcutaneous tissue disorders			rash	pruritus, urticaria

*Gastrointestinal disorders are mainly associated with the underlying disease. Similar or lower incidences compared to placebo were reported for abdominal pain and diarrhoea.

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

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 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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

100 g, 250 g and 300 g white polypropylene securitainer with a white polyethylene cap and a patient information label-leaflet attached.

A 5 ml graduated measuring spoon (PP resin) is included inside the container. The 5 ml measuring spoon is graduated as 1.25 ml, 2.5 ml and 5 ml, it can be used to measure the doses of 1.25 ml and 2.5 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Essential Pharmaceuticals Limited
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Surrey, TW20 8RN,
UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 41094/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13/11/1985

Date of latest renewal: 28/11/2003

10 DATE OF REVISION OF THE TEXT

24/12/2021