SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pancrex V Forte Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pancreatin BP to provide enzymatic activity per tablet not less than:

Free protease	330 BP units
Lipase	5600 BP units
Amylase	5000 BP units

3 PHARMACEUTICAL FORM

Tablet.

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

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

Pancrex 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 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.

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 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, povidone, stearic acid, Opaseal P17-28901 (containing IMS, titanium dioxide (E171), polyvinyl acetate phthalate, and stearic acid (E570)) talc, sucrose, acacia, calcium carbonate, titanium dioxide, Opalux AS 7000B (containing sucrose, sodium benzoate (E211), titanium dioxide (E171), and indigo carmine aluminium lake (E132)), syrup, Opagloss 6000P (containing ethanol, shellac (E904), white beeswax (E901), yellow carnuba wax (E903)).

This medicinal product contains approximately 0.13g of lactose. When taken according to the dosage recommendations each dose supplies up to 1.3g of lactose.

6.2 Incompatibilities

None known

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at a temperature not exceeding 15°C.

6.5 Nature and contents of container

Securitainer: 100, 250, 300 and 500 tablets.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Essential Pharmaceuticals Limited
8a Crabtree Road, Egham,
Surrey, TW20 8RN,
UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 41094/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/11/1985 / 28/11/2003

10 DATE OF REVISION OF THE TEXT

08/09/2015