

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Pancrex V Tablets.

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

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

Free protease	110 BP units
Lipase	1900 BP units
Amylase	1700 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

5 - 15 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](http://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 0.055g of lactose. When taken according to the dosage recommendations each dose supplies up to 0.83g 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, 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 41094/0007

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

30/10/1985 / 28/11/2003

**10 DATE OF REVISION OF THE TEXT**

08/09/2015