PANZYTRAT™ 25000 Capsules
Product Information

DESCRIPTION
PANZYTRAT™ 25000 is a porcine pancreatic enzyme preparation of encapsulated enteric-coated microtablets containing pancreas extract concentrated as pancrelipase.

Each capsule contains 500 mg of pancrelipase enteric-coated microtablets. Minimum enzyme activities in each capsule are: Lipase 25,000 BP Units, Amylase 22,500 BP Units, and Protease 1,250 BP Units. Inactive ingredients include lactose, microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, methacrylic acid copolymer, triethyl citrate, talc, simethicone, gelatin, erythrosine CI45430, iron oxide red CI77491, iron oxide yellow CI77492 and montan wax.

Each microtablet in the capsules is identical with nominal enzyme activity of:

Lipase	400 BP Units	Protease	20 PH Eur Units
Amylase	360 BP Units		

The PANZYTRAT™ 25000 Capsule contains no less than:

Lipase	25,000 BP Units	Protease	1,250 Ph Eur Units
Amylase	22,500 BP Units	Enteric-coated	Yes - Microtablets

PHARMACOLOGY
Administered orally, PANZYTRAT™ 25000 assists in the digestion of fats, carbohydrates and proteins. PANZYTRAT™ 25000 has been specially formulated to combine the features of rapid, homogeneous distribution with the chyme in the stomach, with resistance to inactivation by gastric acid and rapid dissolution in the alkaline pH of the duodenum. This is achieved by enteric-coated microtablets which are released in the stomach following dissolution of the gelatin capsule. The microtablets are of uniform size, shaped for maximum contact surface area (2mm diameter convex tablets of thickness 1.90 – 2.10mm), and mix with the chyme while being protected from inactivation by gastric acid (pH 1). They pass into the alkaline pH of the duodenum at least as quickly as the food they are intended to digest. The enteric coating rapidly dissolves in the duodenum. The duodenal liquid then acts on the uncoated microtablets releasing enzymes at the appropriate site to support the exocrine function of the diseased and insufficient pancreas.

INDICATIONS
PANZYTRAT™ 25000 is indicated for pancreatic enzyme replacement in patients aged 18 months or more suffering with conditions associated with pancreatic exocrine insufficiency such as cystic fibrosis, chronic pancreatitis, post pancreatectomy, post-gastrointestinal bypass surgery (e.g. Billroth II gastroenterostomy) and ductal obstruction.

CONTRAINDICATIONS
PANZYTRAT™ 25000 is contraindicated during the early stages of acute pancreatitis, and acute attacks in chronic pancreatitis, and in those patients who are known to be hypersensitive to porcine protein or any other ingredient of this preparation.

WARNING
Fibrosis colonopathy – Fibrosing colonopathy has been reported in cystic fibrosis patients treated with some high-dose enzyme supplements. Although causation has not been established, patients who continue to use very high dosages wand who have a medical history of gastrointestinal complications should be reviewed regularly (e.g. by ultrasound).

PRECAUTIONS – *Check the following before use*
In general, low-dose preparations should be used in preference to high-dose products. High-dose preparations may be considered in patients who may benefit from higher total enzyme activity and those who are experiencing continued symptoms due to poor compliance because of the number of low-dose capsules necessary per meal.
Neither the PANZYTRAT™ 25000 capsule nor the microtablets should be crushed or chewed. In the case of difficulty in swallowing the capsule, it may be carefully opened and the enteric-coated microtablets taken with liquid during the intake of food, or shaken onto soft food that does not require chewing, and swallowed immediately. Food having a pH of more than 5.5 can dissolve the protective enteric-coating of the microtablets. (See Dosage and Administration.)

The presence of porcine parvovirus cannot be totally excluded in medicines containing extracts of pancreatic powder of porcine origin. However, porcine parvovirus is not regarded as being able to be transmitted to humans nor of causing illness in humans. The presence of porcine parvovirus may indicate the presence of other porcine viruses. However, no cases of transmission of an infectious illness have been reported in association with the use of porcine pancreatic powder extracts.

***Use in pregnancy* –** Safe use in pregnancy has not been established. Therefore, PANZYTRAT™ 25000 should not be used in the first trimester of pregnancy unless; in the judgement of the physician the expected benefits outweigh the potential hazards.

***Use during lactation* –** It is not known whether any of the components of PANZYTRAT™ 25000 are excreted in breast milk or have a harmful effect on the newborn. Therefore, PANZYTRAT™ 25000 should only be used by women who are breast-feeding, if the expected benefits outweigh the potential risks.

***Interactions with other drugs* –** Antacids should not be taken concomitantly with PANZYTRAT™ 25000 as the alkaline pH may break down the enteric – coating. If antacid administration is considered necessary, it is recommended that at least one hour elapse between the intakes of antacid and PANZYTRAT™ 25000.

ADVERSE REACTIONS

Diarrhoea, constipation, abdominal discomfort, nausea and skin reactions have been reported infrequently. Bowel stricture formation has occasionally been reported in children with cystic fibrosis taking high lipase pancreatic enzyme supplements, and should be considered if abdominal symptoms develop (See 'Warnings').

DOSAGE AND ADMINISTRATION

Unless otherwise prescribed by the physician, the following doses apply:

Adults and Children (from 18months of age):	Initially one capsule with every meal and snack
Adults:	6 Capsules daily with food
Children, older than 18 months:	4 Capsules daily with food
Children older than 18months with cystic fibrosis:	1500- 6000 BP units lipase/kg body weight/meal

The dosage should be adjusted according to the severity of the disease and the composition of the food. Care should be taken, in the case of cystic fibrosis patients, that the dose does not exceed that required for adequate fat absorption. Some patients may require much higher doses than shown above. Where there is total pancreatic insufficiency the entire daily requirement for lipase must be substituted, generally up to 400, 000 lipase units daily.

Any increases in dosage should be conducted under medical supervision and with the aim of improving symptoms (e.g., steatorrhoea, abdominal pain). The maximum recommended daily dose of lipase is 20,000 BP units per kg body weight. Dose increases should be added slowly with adequate hydration at all times (approx. 100ml of fluid with each dose). Patients requiring higher dosages should be reviewed regularly.

Agents which increase gastric pH, such as H^2- antagonists and proton pump inhibitors, have been reported to increase the activity of administered pancreatic lipase. This is not an approved indication for these agents. Prescribers should decide, on the basis of the published evidence, whether or not to use them in this way, The capsules can be swallowed whole, or they may be opened and the microtablets taken with fluid or soft food but without chewing. If the microtablets are mixed with food it is important that they are taken immediately to avoid dissolution of the enteric coating.

OVERDOSE - Neither overdoseage nor accidental poisoning has been reported,
PRESENTATION - PANZYTRAT™ 25000: Packs of 100 capsules.
STORAGE- Store below 25°C in a dry place. Keep the container tightly closed.

SPONSOR - Technipro Marketing Pty Ltd, 10/13 Berry Street, CLYDE NSW 2142

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