Package Insert

For the use only of a Registered Medical Practitioner or Hospital or a Laboratory use only

MEEFON 25000
(Pancreatin capsules 300mg)

Composition:

Each Hard gelatin capsule contains:
Pancreatin (as enteric coated pellets) 300mg Equivalent to:
Lipase 25000 IU
Amylase 18000 IU
Protease 1000 IU

Description:

Hard, gelatin capsule size '0', Body: Clear transparent, Cap: Red transparent, Content of capsule – White to creamy enteric coated pellets

Indications:

Exocrine pancreatic enzyme deficiency as in cystic fibrosis, chronic pancreatitis, post pancreatectomy, post gastro-intestinal bypass surgery (eg Billroth II gastroenterostomy), and ductal obstruction from neoplasm (eg of the pancreas or common bile duct). Also used in the treatment of pancreatic exocrine insufficiency.

Pharmacodynamic properties

Multienzymes (amylase, lipase, protease),

The capsules dissolve rapidly in the stomach releasing plenty of minimicrospheres, a multi dose principle which is designed to achieve good mixing with the chyme, emptying from the stomach together with the chyme and after release, good distribution of enzymes within the chyme.

When the minimicrospheres reach the small intestine the coating rapidly disintegrates (at pH > 5.5) to release enzymes with lipolytic, amylolytic and proteolytic activity to ensure the digestion of fats, starches and proteins. The products of pancreatic digestion are then either absorbed directly, or following further hydrolysis by intestinal enzymes.

Pharmacokinetic properties

Pharmacokinetic data are not available as the enzymes act locally in the gastro-intestinal tract. After exerting their action, the enzymes are digested themselves in the intestine.

Contra-indications:

Hypersensitivity to pancreatin of porcine origin or to any of the excipients.

Special Warning and Precaution 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.

There isn't enough information about the safety of using pancreatin during pregnancy and breast-feeding. It's best to avoid use unless you have been diagnosed with pancreas problems that make use of pancreatin essential.

Drug Interaction:

Acarbose (Precose, Prandase) interacts with PANCREATIN

Acarbose (Precose, Prandase) is used to help treat type 2 diabetes. Acarbose (Precose, Prandase) works by decreasing how quickly foods are broken down. Pancreatin seems to help the body break down some foods. By helping the body break down foods pancreatin might decrease the effectiveness of Acarbose (Precose, Prandase).

Side-effects:

Pancreatin can cause nausea, vomiting, diarrhea, mouth and skin irritation, and allergic reactions. High doses can cause problems such as high blood levels of a substance called uric acid, as well as colon damage.

Known symptoms of over dosage and particulars of its treatment:

Symptoms and signs

Chronic high doses of pancreatic enzyme products have been associated with fibrosing colonopathy and colonic strictures. High doses of pancreatic enzyme products have been associated with hyperuricosuria and hyperuricaemia, and should be used with caution in patients with a history of hyperuricaemia, gout or renal impairment.

Pregnancy and lactation

Pregnancy

For pancreatic enzymes no clinical data on exposed pregnancies are available.
Animal studies show no evidence for any absorption of porcine pancreatic enzymes. Therefore, no reproductive or developmental toxicity is to be expected.
Caution should be exercised when prescribing to pregnant women.

Lactation

No effects on the suckling child are anticipated since animal studies suggest no systemic exposure of the breast-feeding woman to pancreatic enzymes. Pancreatic enzymes can be used during breast-feeding.

If required during pregnancy or lactation Meefon 25000 should be used in doses sufficient to provide adequate nutritional status.

Overdose

Extremely high doses of pancreatin have been reported to be associated with hyperuricosuria and hyperuricaemia.

Supportive measures including stopping enzyme therapy and ensuring adequate rehydration are recommended.

Dosage and directions for use:
As directed by the physician.

Storage conditions and period.

Do not store above 25°C. Store in the original package and keep the blisters in the outer carton in order to protect from light and moisture.

Storage life is 2 years.
The preparation should not be used after the expiry date.

Packing.

10 Capsules in Alu /Alu pack and 2 such blisters are packed. in a carton

Manufactured by:

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