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

Abbreviated Prescribing information for ENZAR FORTE (Pancreatin I.P. containing 15,000 U.S.P. units of amylase activity, 4,000 U.S.P. units of lipase activity and 15,000 U.S.P. units of protease activity, sodium tauroglycocholate B.P.C. 1954 65 mg)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Tablets consist of pancreatin with a balanced formula of amylase, lipase & protease activity for complete digestion of carbohydrates, fats & proteins and sodium tauroglycocholate (bile salt) for improved absorption of fat & fat-soluble vitamins.

INDICATION: For indigestion, flatulence, anorexia, dyspepsia, hepatic and pancreatic insufficiency, cystic fibrosis of pancreas, post-operative digestive upsets and convalescence.

DOSAGE AND ADMINISTRATION: As a digestive enzyme: 1 tablet to be sucked (not chewed) for few seconds and then swallowed with every meal. In pancreatic insufficiency: Up to 2 tablets 2-3 times a day can be given, but dosage is individualized depending on patient's pancreatic function.

CONTRAINDICATION: Patients known to be hypersensitive to pork protein and in patients under treatment for acute pancreatitis or acute exacerbations of chronic pancreatic disease.

WARNINGS & PRECAUTIONS: Discontinue the medication if hypersensitivity occur during treatment and treat patient symptomatically. Cases of intestinal stricture and blockage requiring surgical decompression have been reported in cystic fibrosis patients, especially in patients with a history of intestinal complications such as meconium ileus equivalent, short bowel syndrome, surgery or Crohn's disease, who were taking high lipase activity pancreatic enzyme preparations. If symptoms suggestive of gastrointestinal obstruction occur, the possibility of bowel strictures should be considered including evaluation of pancreatic enzyme therapy.

DRUG INTERACTIONS: Interact with antacids containing calcium carbonate or magnesium hydroxide and iron when administered concomitantly.

ADVERSE REACTIONS: Most frequently reported adverse reactions are gastrointestinal in nature, which may include nausea, vomiting, bloating, cramping, constipation or diarrhea, Skin rash, Burning sesnsation around mouth and anus, Acute toxicity, Less frequently, allergic-type reactions have also been observed. Extremely high doses of exogenous pancreatic enzymes have been reported to be associated with hyperuricosuria and hyperuricemia.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/ ENZAR FORTE/MAY 21/02/ABPI

(Additional information is available on request)