ENZAR-HS

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

Abbreviated Prescribing information for ENZAR-HS [Pancreatin—Lipase activity 25000 Ph. Eur. units, Amylase activity 20000 Ph. Eur. units and Protease activity 1000 Ph. Eur. units] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: It is a combination of three enzymes: lipase, protease and amylase. The buffer stabilized pancreatic enzyme in Enzar-HS capsules is enteric-coated with a gastric acid resistant polymer to protect the enzymes during gastric transit into the duodenum.

INDICATION: It is indicated for patients with exocrine pancreatic enzyme insufficiency such as: chronic pancreatitis, post pancreatectomy, post-gastrointestinal bypass surgery (e.g. Billroth II gastroenterostomy), ductal obstruction from neoplasm (e.g. of the pancreas or common bile duct). Enzyme replacement therapy in patients who do not produce enough pancreatic enzymes because of cystic fibrosis, chronic pancreatitis, postpancreatectomy, ductal obstructions caused by cancer of pancreas or common bile duct, pancreatic insufficiency; treatment of steatorrhea of malabsorption syndrome; postgastrectomy or after GI surgery; pancreatic function testing.

DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the exocrine pancreatic insufficiency. Begin therapy with one or two capsules with meals or snacks and adjust dosage according to symptoms. It is important to ensure adequate hydration of patients at all times while taking it. Adults: Per oral take 1 to 3 capsules with each meal or snack. In severe deficiencies, increase the dose up to 8 capsules with meals or increase the frequency to hourly intervals if nausea, cramps, or diarrhea do not occur. Do not crush or allow chew enteric-coated formulations. Give with or before meals. If powder spills on hands, wash with soap or water immediately. Where swallowing of capsules is difficult, the capsules may be carefully opened and the spheres shaken onto a small quantity of soft food such as apple sauce, gelatin, jelly, pudding, etc., which does not require chewing, and swallowed immediately, followed by a glass of water or juice to ensure complete swallowing. Prolonged contact of the spheres with foods having a pH greater than 5.5 can weaken the integrity of the protective enteric coat and compromise the potency of the enzymes.

CONTRAINDICATION: Contraindicated in patients with known hypersensitivity to pork protein, under treatment of acute pancreatitis or acute exacerbation of chronic pancreatitis disease.

WARNINGS & PRECAUTIONS: Use with cautions or stop it if developed hypersensitivity and for intestinal stricture and blockage requiring surgical decompression 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 and gastrointestinal obstruction.

DRUG INTERACTIONS: Antacids: Calcium carbonate or magnesium hydroxide may negate beneficial effect of enzymes. Iron: Serum iron response to oral iron may be decreased with concomitant pancreatic enzyme administration.

ADVERSE REACTIONS: Nausea, vomiting, bloating, cramping, constipation or diarrhea, allergic-type reactions, hyperuricosuria and hyperuricemia.

MARKETED BY:



IN/ ENZAR-HS/FEB 2015/01/AbPI

(Additional information is available on request)