

# ENZYSTAL

(Digestive Enzyme Tablets)

## DESCRIPTION

Pancreatin is obtained from pancreas of Hog or Ox. It is white or buff coloured amorphous powder free of unpleasant odor. Hemicellulase are large group of polysaccharides found in association with legnin in the primary and secondary cell walls of all plants and some sea woods. Extract Fellis Bovis (bile constituents are dark yellowish green mass with a disagreeable bitter taste. They consist of sodium glycocholate and taurocholate.

## CLINICAL PHARMACOLOGY

### Pharmacodynamics

The constituents of pancreatin 1) protease helps in digestion of proteins by converting them into proteases 2) lipase hydrolyses fats to glycerol and fatty acids and 3) amylase converts starch into dextrin and sugars. The site of action of pancreatin is in the duodenum and upper jejunum. For protecting it from acid inactivation it is given as enteric coated tablets immediately after meals. Bile acids in bile exist as conjugate. They facilitate absorption of fats by enhancing the diffusion of the solubilized fat digestion products through the layer of water that coats intestinal mucosa. The bile acids are reabsorbed mainly by the ileum by active transport and returned to the liver where they are efficiently extracted and re-excreted in bile. The bile acid pool, that is, the mass of bile acids in the enterohepatic circulation, circulates six to ten times a day. The only input of bile acids into enterohepatic circulation is by synthesis from loss is by faecal excretion.

### Pharmacokinetics

Since the actions of all the constituents of Enzystal are restricted to gastrointestinal tract, no blood level studies are relevant and useful in judging the onset and duration of action of this preparation. Pancreatin is rapidly and irreversibly inactivated by gastric acid and pepsin. In addition, a relative lack of bicarbonate secretion by the pancreas may predispose to a low pH in the intestine. Administration of sodium bicarbonate with Enzystal would lessen steatorrhoea in chronic pancreatitis. In vitro activity of Enzystal parallels clinical effectiveness.

## INDICATIONS

Enzystal is indicated to reduce symptoms of indigestion caused by irregular or too abundant nutrition (overconsumption of fat, smoked, fried, unusual or usual badly chewed foods). The preparation normalizes the functioning of the gastrointestinal tract, stimulates the assimilation of vitamins A, D, E and K, food digestion in elderly patients.

## CONTRAINDICATIONS

Hypersensitivity to pancreatin, complete biliary obstruction and jaundice.

## WARNINGS AND PRECAUTION

The recommended dose of Enzystal should not be exceeded. Consult your physician if administration of Enzystal does not remove indigestion symptoms. Keep the preparation out of reach of children. The use of Enzystal should not be used in case of mechanical jaundice or hepatitis. Acute abdomen with suspected appendicitis.

## CARCINOGENESIS/ REPRODUCTION TOXICITY

No relevant information additional to that contained elsewhere in the leaflet.

## DRUG INTERACTIONS

- Simultaneous administration of cimetidine or antacids improve the action of pancreatin which is protected from destruction by gastric acidity.
- The bioavailability of iron preparations is reduced if given with pancreatin enzymes.

## OVERDOSAGE

No overdoses have been reported.

## ADVERSE EFFECTS

Buccal and perianal soreness in infants. Hypersensitivity reactions consisting of sneezing, lacrimation, skin rashes or bronchospasm. High doses may cause nausea, abdominal cramps or diarrhoea (loose stools). Blood uric acid level may increase, resulting in uricosuria.

**Inform your doctor in case of any adverse reactions related to drug use.**

## DOSAGE AND ADMINISTRATION

### Dosage:

1 - 2 tablets 3 times a day, to be swallowed whole during or immediately after meals.

Swallow whole tablet. Do not crush or chew.

**Method of administration:** Oral

## STORAGE

Store below 25°C, protected from light and moisture.

## PRESENTATION

Enzystal is available as sugar enteric-coated tablets in blister strip of 10 tablets.



Manufactured by :  
TORRENT PHARMACEUTICALS LTD.  
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