

ENZAR-HS

1. Generic Name

Pancreatin Gastro-Resistant Capsules B.P.

2. Qualitative and quantitative composition

Each hard gelatin capsule contains:

Pancreatin I.P. (as enteric coated pellets)

Equivalent to

Lipase activity.....25000 Ph.Eur Units

Amylase activity....18000 Ph.Eur Units

Protease activity.....1000 Ph.Eur Units

Approved colours used in hard gelatin capsule shells.

The excipients are ready to use pellets and Talc.

3. Dosage form and strength

Dosage Form: Hard Gelatin Capsules

Strength: Lipase activity – 25000 Ph Eur Units, Amylase activity - 18000 Ph Eur Units,

Protease activity - 1000 Ph Eur Units

4. Clinical particulars

4.1 Therapeutic indication

Enzar-HS capsules are indicated for patients with exocrine pancreatic enzyme insufficiency such as: chronic pancreatitis, postpancreatectomy, 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.

4.2 Posology and method of 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. Dose increases, if required, should be made slowly, with careful monitoring of response and symptomatology. It is important to ensure adequate hydration of patients at all times while taking Enzar-HS.

Adults

Per oral take 1 to 3 capsules with each meal or snack. In severe deficiencies, increase the dose to 8 capsules with meals or increase the frequency to hourly intervals if nausea, cramps or diarrhoea do not occur.

4.3 Contraindications

Hypersensitivity to the active ingredient (porcine pancreatin) or any of the excipients.

4.4 Special warnings and precautions for use

It is possible that some irritation of the skin of the mouth may occur if capsules are chewed or the contents retained in the mouth. Irritation of the anus may also occur. A barrier cream may prevent this local irritation.

Allergic/asthmatic reactions have occasionally occurred on handling the capsule contents. If the capsule contents are mixed with liquids or feeds the resulting mixture should not be allowed to stand for more than one hour prior to use.

4.5 Drugs interactions

None known.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

It should not be used in pregnancy and lactation unless clearly necessary but if required should be used in doses sufficient to provide adequate nutritional status.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Rare cases of hyperuricosuria and hyperuricaemia have been reported when extremely high doses of pancreatin have been taken.

Strictures of the ileo-caecum and large bowel, and colitis, have been reported in children with cystic fibrosis taking high doses of pancreatic enzyme supplements. To date Pancreatin and Pancreatin presentations have not been implicated in the development of colonic damage. However unusual abdominal symptoms or changes in abdominal symptoms should be reviewed to exclude the possibility of colonic damage especially if the patient is taking in excess of 10,000 units/kg/day of lipase.

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

4.9 Overdose

None Stated.

5. Pharmacological properties

5.1 Mechanism of Action

Pancreatin improve the ability to metabolise starches, proteins and fats.

5.2 Pharmacodynamic properties

Pancreatin is derived from porcine pancreas and contains the enzymes, amylase, protease and lipase. The enzymes have the same actions as pancreatic juice and when administered to patients with pancreatic insufficiency improve the ability to metabolise starches, proteins and fats.

5.3 Pharmacokinetic properties

Pancreatin hydrolyses fats to glycerol and fatty acids, changes proteins into proteases and derived substances, and converts starch into dextrins and sugars.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

No relevant pre-clinical safety data has been generated.

7. Description

Pancreatin is a preparation of mammalian pancreas containing protease, lipase and amylase activity. It may contain sodium. Pancreatin is a white to buff coloured amorphous powder; odour meaty and unpleasant. Pancreatin is soluble in water producing a slightly turbid solution; practically insoluble in ethanol (95%); and in ether.

Pancreatin Gastro-Resistant Capsules are Dark Blue clear transparent size '1' hard gelatin capsule filled with beige brown pellets. The excipients are ready to use pellets and Talc.

8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable.

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

Enzar HS is available in five blister strips of 10 capsules each.

8.4 Storage and handling instructions

Store in a cool, dry place. Keep out of reach of children.

9. Patient Counselling Information

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine is available without prescription. However, you still need to take Enzar HS carefully to get the best results from it. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

9.1 What Enzar-HS is and what it is used for

9.2 What you need to know before you use Enzar-HS

9.3 How to use Enzar-HS

9.4 Possible side effects

9.5 How to store Enzar-HS

9.6 Further information

9.1 What Enzar-HS is and what it is used for

The active ingredient in Enzar-HS is Pancreatin.

Pancreatin is a combination of enzymes normally produced by the pancreas which help to digest protein, fat, starch and sugars in the food that you eat.

Enzar-HS capsules are indicated for patients with exocrine pancreatic enzyme insufficiency such as: chronic pancreatitis, postpancreatectomy, 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.

9.2 What you need to know before you use Enzar-HS

Do not take Enzar-HS if you:

- are allergic (hypersensitive) to pancreatin or any of the other ingredients of Enzar-HS.

There are no known diseases that may prevent you from taking Enzar-HS.

Taking other medicines

Enzar-HS are not known to interfere with any other medicines that you may be taking. However if you are prescribed another medicine, inform the doctor you are taking Enzar-HS.

Pregnancy and breast-feeding

If you are pregnant, thinking of becoming pregnant or breast-feeding, discuss this with your doctor before taking your medicine as dose adjustments may be necessary. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Enzar-HS do not interfere with your ability to drive or operate machinery.

9.3 How to use Enzar-HS

Dosage

Your doctor or pharmacist will advise you on the amount of Enzar-HS to take before each meal, although you may find with experience that you need to adjust the dose according to the size and type of meal that you eat. If loose pale stools (faeces) occur you may need to increase the dose. Always check with your pharmacist if you are not sure.

The following should provide a good starting point for adjustment of the dose:

- For infants, the contents of 1-2 capsules mixed with feeds.
- For older children and adults, 2-6 capsules (or their contents) with each meal or snack.

If the capsule contents are mixed with liquids or feeds, use within one hour.

If you take more Enzar-HS than you should

There are no special precautions to take, although the use of a barrier cream may help prevent possible irritation of the anus.

If you forget to take Enzar-HS

Simply skip that dose and take the next dose with your next meal or snack.

If you have any further questions on the use of this product, ask your pharmacist

9.4 Possible Side Effects

Like all medicines, Enzar-HS can cause side effects, although not everybody gets them. It is possible that some people may be allergic (hypersensitive) to Enzar-HS. Allergic/asthmatic reactions have occasionally occurred on handling the capsule contents.

Signs of an allergy to something include rash, wheezing, breathlessness, swollen eyelids, face or lips, and in extreme cases collapse. In the unlikely event that you should get any of these symptoms soon after taking Enzar-HS, don't take any more. Tell a doctor straight away and take the packaging and this leaflet with you.

Rarely, high levels of uric acid in the blood and urine have been reported when extremely high doses of pancreatin have been taken.

Narrowing of parts of the bowel, and inflammation of the colon, have been reported in children with cystic fibrosis taking high doses of pancreatic enzyme supplements. Some irritation of the skin of the mouth may occur if the capsules are chewed or the contents kept in the mouth. Irritation of the anus may also occur, which may be prevented by use of a barrier cream.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

9.5 How to store Enzar-HS

- Keep out of the sight and reach of children.
- Do not use the tablets after the expiry date stated on the carton (EXP).
- Store in a cool, dry place.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

9.6 Contents of the pack and other information

What Enzar-HS contains:

- The active substance is Pancreatin I.P. (as enteric coated pellets) Equivalent to,
Lipase activity.....25000 Ph.Eur Units
Amylase activity....18000 Ph.Eur Units
Protease activity.....1000 Ph.Eur Units
- The excipients are ready to use pellets and Talc.

What are the contents of the pack

They are available in blister strips of 10 capsules.

10. Details of manufacturer

Manufactured by:

Windlas Biotech Pvt. Limited,
(Plant-2) Khasra No. 141-143 & 145, Mohabewala Industrial Area,
Dehradun – 248110, Uttarakhand.

11. Details of permission or licence number with date

Mfg Lic No. 55/UA/SC/P-2013 issued on 02.04.2019

12. Date of revision

Nov 2019

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

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