

ENZAR FORTE

1. Generic Name

Pancreatin and Sodium Tauroglycocholate Tablets

2. Qualitative and quantitative composition

Each enteric coated tablet contains:

Pancreatin I.P.

(Containing 15,000 U.S.P. units of Amylase activity

4,000 U.S.P. units of Lipase activity

15,000 U.S.P. units of Protease activity)

Sodium Tauroglycocholate B.P.C 1954.....65 mg enteric coated tablets

With a sugar coating containing essential carminative oils

Colour: Titanium Dioxide I.P.

The excipients used are Lactose, Stearic Acid, Povidone, Tragacanth, Magnesium Stearate, Glycerol Mono-oleate, Ethyl Cellulose, Isopropyl Alcohol, Talc, Light Kaolin, Gelatin, Sucrose, Gum Acacia, Cellulose Acetate Phthalate, Acetone, Sodium Carboxymethyl Cellulose, Titanium Dioxide, Polysorbate 80, Colloidal Silicon Dioxide, Ginger, Cinnamon Oil, Cardamom Oil, Clove Leaf Oil, Dioctyl Sodium Sulphosuccinate and Carnuba Wax.

3. Dosage form and strength

Dosage form: Tablet

Strength: Pancreatin (**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) and Sodium Tauroglycocholate 65 mg

4. Clinical particulars

4.1 Therapeutic indication

Indigestion, flatulence, anorexia, dyspepsia, hepatic and pancreatic insufficiency, cystic fibrosis of pancreas, post-operative digestive upsets and convalescence.

4.2 Posology and method of administration

- Always use these tablets exactly as your health care provider has told you.
- You should check with your health care provider if you are unsure of the instructions.

Adults (including the elderly) and children:

Initially, one or two tablets during or immediately after each meal. Tablet to be swallowed whole. Dose increases, if required, should be added slowly, with careful monitoring of response and symptomatology.

It is important to ensure adequate hydration of patients at all times.

4.3 Contraindications

ENZAR FORTE is contraindicated in patients known to be hypersensitive to pork protein. ENZAR FORTE is contraindicated in patients under treatment for acute pancreatitis or acute exacerbations of chronic pancreatic disease.

4.4 Special warnings and precautions for use

Unsuitable for people with lactase insufficiency, galactosaemia or glucose/galactose malabsorption syndrome.

Variations in response to treatment may be due to enteric coating. It is possible that some irritation of the skin of the mouth may occur if tablets are chewed or preparations retained in the mouth. Irritation of the anus may also occur. A barrier cream may prevent this local irritation.

Hypersensitivity occurs during the course of treatment, discontinue medication and treat 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.

4.5 Drugs 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**.

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

ENZAR FORTE 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

In reported clinical trials, the most commonly reported adverse reactions were gastrointestinal disorders and were primarily mild or moderate in severity.

The following adverse reactions have been observed during clinical trials with the below indicated frequencies;

Organ system	Very common ≥ 1/10	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1000 to < 1/100	Frequency not known

Gastrointestinal disorders	abdominal pain*	nausea, vomiting, constipation, abdominal distension, diarrhoea*		strictures of the ileo-caecum and large bowel (fibrosing colonopathy)
Skin and subcutaneous tissue disorders			rash	pruritus, urticaria
Immune system disorders				hypersensitivity (anaphylactic reactions).

*Gastrointestinal disorders are mainly associated with the underlying disease. Similar or lower incidences compared to placebo were reported for abdominal pain and diarrhoea.

Strictures of the ileo-caecum and large bowel (fibrosing colonopathy) have been reported in patients with cystic fibrosis taking high doses of pancreatin preparations.

Allergic reactions mainly but not exclusively limited to the skin have been observed and identified as adverse reactions during post-approval use. Because these reactions were reported spontaneously from a population of uncertain size, it is not possible to reliably estimate their frequency.

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 ENZAR FORTE and ENZAR FORTE 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

Reporting suspected adverse reactions after authorisation of the medicinal product important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

4.9 Overdose

Extremely high doses of exogenous pancreatic enzymes have been reported to be associated with hyperuricosuria and hyperuricemia.

Symptoms: Nausea, Vomiting, abdominal cramps diarrhea, hyperuricosuria, hyperuricemia.

5. Pharmacological properties

5.1 Mechanism of Action

Pancreatin and sodium Tauroglycocholate hydrolyse fats to glycerol and fatty acids, break down protein into peptides, proteoses and derived substances, and convert starch into dextrans and sugars.

5.2 Pharmacodynamics properties

Multienzymes (amylase, lipase, protease) ATC code: A09A A02

Pancreatin and sodium Tauroglycocholate hydrolyse fats to glycerol and fatty acids, break down protein into peptides, proteases and derived substances, and convert starch into dextrins and sugars.

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

ENZAR FORTE 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 and Sodium Tauroglycocholate Tablets are white coloured, round biconvex, enteric sugar coated tablets with plain surface on both sides. The excipients used are Lactose, Stearic Acid, Povidone, Tragacanth, Magnesium Stearate, Glycerol Mono-oleate, Ethyl Cellulose, Isopropyl Alcohol, Talc, Light Kaolin, Gelatin, Sucrose, Gum Acacia, Cellulose Acetate Phthalate, Acetone, Sodium Carboxymethyl Cellulose, Titanium Dioxide, Polysorbate 80, Colloidal Silicon Dioxide, Ginger, Cinnamon Oil, Cardamom Oil, Clove Leaf Oil, Diethyl Sodium Sulphosuccinate and Carnauba Wax.

8. Pharmaceutical particulars

8.1 Incompatibilities

None Stated

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

ENZAR FORTE is packed in strip of 15 tablets

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 has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 9.4.

What is in this leaflet?

9.1 What ENZAR FORTE are and what they are used for

9.2 What you need to know before you use ENZAR FORTE

9.3 How to use ENZAR FORTE

9.4 Possible side effects

9.5 How to store ENZAR FORTE

9.6 Contents of the pack and other information

9.1 What ENZAR FORTE are and what they are used for.

The active ingredient in **ENZAR FORTE** Tablets are Pancreatin and SodiumTauroglycocholate. Pancreatin with a balanced formula of Amylase, Lipase & Protease activity for complete digestion of Carbohydrates, Fats & Proteins. The advantage of bile salt i.e. sodium Tauroglycocholate is that it improves absorption of fat & fat-soluble vitamins.

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 FORTE is indicated for the treatment of Indigestion, flatulence, anorexia, dyspepsia, hepatic and pancreatic insufficiency, cystic fibrosis of pancreas, post-operative digestive upsets and convalescence.

9.2 Before You Take ENZAR FORTE Tablets

Do not take ENZAR FORTE Tablets if you

- are allergic (hypersensitive) to Pancreatin and Sodium Tauroglycocholate or any of the other ingredients of **ENZAR FORTE**
- cannot easily digest or absorb milk sugars (lactose, galactose, glucose). Contact your doctor or pharmacist before taking **ENZAR FORTE** if you think this might be the case.

Taking other medicines **ENZAR FORTE** 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 Forte**.

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 FORTE Tablets do not interfere with your ability to drive or operate machinery.
Important information about some of the ingredients of ENZAR FORTE Tablets

This product contains lactose and sucrose. If you are lactose or sucrose intolerant, contact your doctor or pharmacist before taking this product.

9.3 How to use ENZAR FORTE

ENZAR FORTE will be given to you by a health care provider.

- Always use these tablets exactly as your health care provider has told you.
- You should check with your health care provider if you are unsure of the instructions.

Dosage: Initially, one or two tablets during or immediately after each meal. Tablet to be swallowed whole. Dose increases, if required, should be added slowly, with careful monitoring of response and symptomatology.

It is important to ensure adequate hydration of patients at all times.

If you take more ENZAR FORTE 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 FORTE

Simply skip that dose and take the next dose before 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 FORTE** Tablets can cause side effects, although not everybody gets them. It is possible that some people may be allergic (hypersensitive) to **ENZAR FORTE** Tablets. Signs of an allergy to something include rash, wheezing, breathlessness, swollen eyelids, face or lips, and in extreme cases collapse. Other events are

- Nausea
- Vomiting
- Stomach pain
- Stomach upset (Constipation, Diarrhoea)
- Skin rash
- Burning sensation around mouth and anus
- Acute toxicity

In the unlikely event that you should get any of these symptoms soon after taking **ENZAR FORTE** Tablets, 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 tablets are chewed or the contents kept in the mouth. Irritation of the anus may also occur, which may be prevented by use of the 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.

By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store ENZAR FORTE

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

9.6 Contents of the pack and other information

Each enteric coated tablet contains as active ingredients Pancreatin I.P. (Containing 15,000 U.S.P. units of Amylase activity 4,000 U.S.P. units of Lipase activity 15,000 U.S.P. units of Protease activity) and Sodium Tauroglycocholate B.P.C 1954 65 mg with a sugar coating containing essential carminative oils.

The excipients used are Lactose, Stearic Acid, Povidone, Tragacanth, Magnesium Stearate, Glycerol Mono-oleate, Ethyl Cellulose, Isopropyl Alcohol, Talc, Light Kaolin, Gelatin, Sucrose, Gum Acacia, Cellulose Acetate Phthalate, Acetone, Sodium Carboxymethyl Cellulose, Titanium Dioxide, Polysorbate 80, Colloidal Silicon Dioxide, Ginger, Cinnamon Oil, Cardamom Oil, Clove Leaf Oil, Dioctyl Sodium Sulphosuccinate and Carnuba Wax.

ENZAR FORTE is packed in strip of 15 tablets.

10 Details of manufacturer

Manufactured By,

Windlas Biotech Pvt. Limited (Plant-2)

Khasra No. 141-143 & 145, Mohabewala Industrial Area,

Dehradun – 248110, Uttarakhand.

Torrent Pharmaceuticals Ltd.

32 No. Middle Camp, NH-10, East District,

Gangtok, Sikkim – 737 135.

11. Details of permission or licence number with date

Mfg Lic No. 55/UA/SC/P-2013 issued on 03.10.2017

Mfg Lic No. M/564/2010 issued on 23.12.2016

12. Date of revision

MAY 2021

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

IN/ ENZAR FORTE 15,000, 4,000 15,000 U.S.P. units and 65 mg/MAY-21/02/PI