

FIRULIN 10000 (Pancreatin Capsules 150 mg)

(Pancreatin 150 mg)

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What Firulin 10000 Capsules is and what it is used for

Firulin Capsules used for the treatment of pancreatic exocrine insufficiency.

How Firulin 10000 Capsules works

Firulin Capsules contains porcine pancreatin formulated as gastro resistant (acid-resistant) minimicrospheres within gelatin capsules.

The capsules dissolve rapidly in the stomach releasing plenty of minimicrospheres, a multidose principle which is designed to achieve good mixing with the chyme, emptying from the stomach together with the chyme and after release, good distribution of enzymes within the chyme.

When the minimicrospheres reach the small intestines the coating rapidly disintegrates (at pH > 5.5) to release enzymes with lipolytic, amylolytic and proteolytic activity to ensure the digestion of fats, starches and proteins. The products of pancreatic digestion are then either absorbed directly, or following further hydrolysis by intestinal enzymes.

Before you use Firulin 10000 Capsules

- When you must not use Firulin Capsules

Do not take Firulin 10000 Capsules if:

Hypersensitivity to pancreatin of porcine origin or to any of the excipients.

- Before you start to use it

Check with your doctor before using Firulin 10000 Capsules if:

Strictures of the ileo-caecum and large bowel (fibrosing colonopathy) have been reported in patients with cystic fibrosis taking high doses of pancreatin preparations. As a precaution, unusual abdominal symptoms or changes in abdominal symptoms should be medically assessed to exclude the possibility of fibrosing colonopathy, especially if the patient is taking in excess of 10,000 units of lipase/kg/day.

- Taking other medicines

No interaction studies have been performed.

How to use Firulin 10000 Capsules

- How much to use it

Always take Firulin 10000 Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage are individualized according to the degree of maldigestion and severity of the disease.

- When to use it

Always take Firulin 10000 during or immediately after eating a meal and drink plenty of water.

Swallow the capsule in whole or open the capsule and mix the granule (without crushing) with acidic liquid such as apple, orange or pineapple juice. Swallow the mixture straight away without chewing.

Do not hold Firulin 10000 or its content in your mouth.

- How long to use it

You should take your medicine until your doctor tells you to stop. Many patients will need to take pancreatic enzyme supplements for the rest of their lives.

- If you forget to use it

- If you forget to use your Firulin 10000 Capsules, take as soon as you remember. If it nearing the time for next dose, leave out that dose completely and use the next Firulin 10000 Capsules at the usual time.

- Do not take a double dose to make up for a forgotten Firulin 10000 Capsules.

- If you use too much (overdose):

Extremely high doses of pancreatin have been reported to be associated with hyperuricosuria and hyperuricaemia.

Supportive measures including stopping enzyme therapy and ensuring adequate rehydration are recommended

If you take too many Firulin 10000 Capsules than you should, tell a doctor or go to a hospital casualty department straight away.

While you are using it

- Things you must do

Tell your doctor immediately if:

Pregnancy

For pancreatic enzymes, no clinical data on exposed pregnancies are available.

Animal studies show no evidence for any absorption of porcine pancreatic enzymes. Therefore, no reproductive or developmental toxicity is to be expected.

Caution should be exercised when prescribing to pregnant women.

Lactation

No effects on the suckling child are anticipated since animal studies suggest no systemic exposure of the breast-feeding woman to pancreatic enzymes. Pancreatic enzymes can be used during breast-feeding.

If required during pregnancy or lactation Firulin 10000 Capsules should be used in doses sufficient to provide adequate nutritional status.

- Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Firulin 10000 Capsules, or change the dosage, without checking with your doctor.

- Things to be careful of

Driving and using machines

Firulin 10000 Capsules has no or negligible influence on the ability to drive or use machines

Side Effects

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;

Gastrointestinal disorders:

Very common: abdominal pain*

Common: nausea, vomiting, constipation, abdominal distention, diarrhoea*

Not known: strictures of the ileo-caecum and large bowel (fibrosing colonopathy)

Skin and subcutaneous tissue disorders:

Uncommon: rash

Not known: pruritus, urticaria

Immune system disorders:

Not known: 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.

Paediatric population

No specific adverse reactions were identified in the paediatric population. Frequency, type and severity of adverse reactions were similar in children with cystic fibrosis as compared to adults.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Firulin 10000 Capsules

- Storage

Store in dry place, temperature below 30° C.

- Disposal

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.

Product Description

- What it looks like

Hard Gelatin Capsule

Size ' 1 ' hard gelatin capsule having opaque brown cap and clear transparent body containing brownish colored gastro resistant granules.

- Ingredients

Active ingredient:

Each hard gelatin capsule contains:

Gastro resistant granules containing pancreatin 150 mg equivalent to

Lipase – 10000 Ph. Eur. Units

Amylase – 8000 Ph. Eur. Units

Protease – 600 Ph. Eur. Units

Inactive ingredients:

Macrogol, Hypromellose, Isopropyl alcohol, Dichloromethane,

Hypromellose phthalate, Triethyl citrate, Dimethicone and Acetone.

Manufacturer

Kusum Healthcare Pvt. Ltd.

Plot No. M-3, Indore Special Economic Zone, Phase-II, Pithampur, Distt. Dhar, Madhya Pradesh, Pin 454774.

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.

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