FIRULIN 10000
Pancreatin Capsules 150 mg

COMPOSITION:
Each hard gelatin capsule contains:
Gastro-resistant granules of Pancreatin 150 mg equivalent to
Lipase 10,000 Ph.Eur. Units
Amylase 8,000 Ph.Eur. Units
Protease 600 Ph.Eur. Units

Excipients:
Macrogol 8000, Hypromellose, Isopropyl alcohol, Dichloromethane, Hypromellose phthalate, Triethyl citrate, Dimethicone, Acetone & Size '1' empty hard gelatin capsule shell having opaque brown coloured cap and clear transparent body.

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

PHARMACEUTICAL FORM: Hard gelatin capsule

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties:
Pharmacotherapeutic group: Multienzymes (Amylase, Lipase, Protease).
ATC Code: A09AA02
Firulin capsules contains porcine pancreatin formulated as enteric-coated (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 intestine 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.

Pharmacokinetic Properties:
Pharmacokinetic data are not available as the enzymes act locally in the gastro-intestinal tract. After exerting their action, the enzymes are digested themselves in the intestine.

INDICATIONS:
Treatment of pancreatic exocrine insufficiency in paediatric and adult patients often associated with, but not limited to:
- Cystic fibrosis
- Chronic pancreatitis
- Pancreatic surgery
- Gastrectomy

- Pancreatic cancer
- Gastrointestinal bypass surgery (e.g.Billroth II gastroenterostomy)
- Ductal obstruction of the pancreas or common bile duct (e.g. from neoplasm)
- Shwachman-Diamond Syndrome
- For the improvement of digestion and relief of maldigestion symptoms after consumption of a (fatty) meal; like sensation of heaviness, bloating, abdominal distension, abdominal pain/cramping and/or diarrhoea.

DOSAGE & MODE OF ADMINISTRATION:

The posology aims at individual needs and depends on the severity of the disease and the composition of food. It is recommended to take the enzymes during or immediately after the meals.

The capsules should be swallowed intact, without crushing or chewing, with enough fluid during meals or snacks.

When swallowing of capsules is difficult (e.g. small children or elderly patients), the capsules may be carefully opened and the granules added to acidic soft food [pH < 5.5] that does not require chewing, or the pellets will be taken with acidic liquid with [pH < 5.5]. This could be apple sauce or yogurt or fruit juice with a pH less than 5.5, e.g. apple, orange or pineapple juice. This mixture should not be stored. Crushing and chewing of the granules or mixing with food or fluid with a pH greater than 5.5 can disrupt the protective enteric coating. This can result in early release of enzymes in the oral cavity and may lead to reduced efficacy and irritation of the mucous membranes. Care should be taken that no product is retained in the mouth.

It is important to ensure adequate hydration at all times, especially during periods of increased loss of fluids. Inadequate hydration may aggravate constipation. Any mixture of the granules with food or liquids should be used immediately and should not be stored.

Dosing in pediatric and adult patients with cystic fibrosis

Based upon a recommendation of the Cystic Fibrosis Consensus Conference, the US CF Foundation case- control study, and the UK case-control study, the following general dosage recommendation for pancreatic enzyme replacement therapy can be proposed:

▪ Weight-based enzyme dosing should begin with 1 000 lipase units/kg/meal for children less than four years of age and with 500 lipase units/kg/meal for those over age four.

▪ Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status.

▪ Most patients should remain below or should not exceed 10 000 lipase units/kg body weight per day or 4000 lipase units/gram fat intake

Dosing in other condition associated with exocrine pancreatic insufficiency

Dosage should be individualized by patient according to the degree of maldigestion and the fat content of the meal. The required dose for a meal ranges from about 25 000 to 80 000 Ph. Eur. units of lipase and half of the individual dose for snacks.

Dose of 1 to 2 capsules of Firulin 10000 per meal for the improvement of digestion and relief of maldigestion symptoms after consumption of a (fatty) meal (Refer to section Indications).

CONTRAINDICATIONS:

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

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

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

PREGNANCY AND LACTATION:

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 capsules should be used in doses sufficient to provide adequate nutritional status.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Firulin capsules has no or negligible influence on the ability to drive or use machines.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

No interaction studies have been performed.

UNDESIRABLE 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;

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 distention, 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.
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.

OVERDOSE AND TREATMENT:
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.

STORAGE CONDITIONS:
Store in dry place, temperature below 30° C.

SHELF LIFE
24 months

DOSAGE FORM AND PACKAGING AVAILABLE:
10 capsules are packed in an Alu-Alu Blister. Such 1, 3 and 10 blisters are packed in a carton along with pack insert.

NAME AND ADDRESS OF MANUFACTURER:
Kusum Healthcare Pvt. Ltd.
Plot No. M-3, Indore Special Economic Zone,
Phase-II, Pithampur, Distt. Dhar,
Madhya Pradesh, INDIA

PRODUCT REGISTRATION HODER:
Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 1/2 Miles Off Jalan Meru,
41050 Klang, Selangor, Malaysia

DATE OF REVISION OF PACKAGE INSERT
May 2026