Protolan®

Lansoprazole INN 15 mg & 30 mg capsule

Description

Lansoprazole is a proton pump inhibitor. It is an irreversible inhibitor of the parietal cell H^+-K^+ ATPase, which leads to profound inhibition of gastric acid secretion.

Composition

Protolan®-15 : Each capsule contains Lansoprazole INN 15 mg as enteric coated granules.

Protolan®-30 : Each capsule contains Lansoprazole INN 30 mg as enteric coated granules.

Indications

- Duodenal ulcer
- Gastric ulcer
- Esophagitis/Ulceration
- Zollinger-Ellison syndrome
- Resistant ulcers and esophagitis
- Eradication of Helicobacter pylori in the treatment of peptic ulcer (in combination with antibiotics)

Dosage and administration

Benign gastric ulcer : 30 mg daily in the morning for 8 weeks.

Duodenal ulcer : 30 mg daily in the morning for 4 weeks; maintenance 15 mg.

NSAID-associated duodenal or gastric ulcer : 15-30 mg daily for 4 weeks, followed by a further 4 weeks if not fully healed.

Zollinger–Ellison syndrome (and other hyper - secretory conditions) : Initially 60 mg once daily adjusted according to response; daily doses of 120 mg or more is given in two divided doses.

Gastroesophageal reflux disease : 30 mg daily in the morning for 4 weeks, followed by a further 4 weeks if not fully healed; maintenance 15-30 mg daily.

Acid-related dyspepsia : 15-30 mg daily in the morning for 2-4 weeks.

Contraindication

The use of Protolan is contraindicated in patients with a history of hypersensitivity to any of the ingredients of Protolan capsule.

Adverse reactions

Potentially life-threatening effects : None has been recorded.

Acute overdosage : None has been reported.

Severe or irreversible adverse effects : The possible induction of carcinoid tumors by profound acid suppression, and a rise in serum gastrin may occur. There is a rise in serum gastrin levels in the first 3 months of treatment, which are then maintained though at a lower level than those found in pernicious anaemia. Long- term treatment with a proton pump inhibitor in patients with Helicobacter pylori infection may accelerate the development of atrophic gastritis.

Symptomatic adverse effect : Dose dependent diarrhoea occurs with an incidence of about 4% at 30 mg per day, rising to 8% at 60 mg per day. Headache occurs in 2-3% of treated patients.

Interference with clinical pathology test: None is known.

High risk groups

Neonates : There is no relevant human data. The drug is not recommended for use with neonates.

Children : The youngest person to have received Lansoprazole in clinical trials was 13 years old.

Pregnant women : There is no relevant human data.

The Elderly : No problems have been encountered in clinical use and there has been no increase in adverse drug reaction in the elderly.

Drug interactions

Lansoprazole appears to be a selective inhibitor of the cytochrome P450 monooxygenase system; there may be an effect on hepatic clearance, but there have been no reports to date of clinically relevant interactions. There is some uncertainty over the effect of Lansoprazole on the oral combined contraceptive pill.

Commercial pack

Protolan®-15 : Box containing 3 x 10's capsules in blister strip.

Protolan®-30 : Box containing 3 x 10's capsules in blister strip.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH

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