

LANSOPRAZOLE (Systemic)

Indications

Accepted

Gastroesophageal reflux disease [GERD] (prophylaxis and treatment) 3, 4, 6, 9, 13, 16, 18, 24, 30, 33, 35, 36, 37 ¼ Lansoprazole is indicated for the short-term treatment of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) 36.

Lansoprazole is indicated for the short-term (up to 8 weeks) treatment for symptom relief and healing of all grades of erosive esophagitis (associated with GERD) 36.

Lansoprazole may be indicated for an additional 8 weeks of treatment in patients in whom healing has not occurred 1, 36.

If erosive esophagitis recurs, an additional course of lansoprazole treatment may be considered 1, 36.

Lansoprazole also is indicated to maintain healing of erosive esophagitis 36.

Ulcer, gastric (treatment) 3, 4, 6, 9, 13, 16, 18, 24, 30, 33, 35, 36, 37 ¼ Lansoprazole is indicated for short-term (up to 8 weeks) treatment in patients with active benign gastric ulcer 30, 36.

Ulcer, duodenal (prophylaxis and treatment) 1, 3, 4, 5, 6, 10, 13, 14, 16, 18, 22, 24, 26, 36, 37 ¼ Lansoprazole is indicated for short-term (up to 4 weeks) treatment for symptom relief and healing in patients with active duodenal ulcer 1, 36.

Lansoprazole also is indicated to maintain healing of duodenal ulcers 36.

Ulcer, duodenal, Helicobacter pylori -associated (treatment) 3, 4, 6, 9, 13, 16, 18, 24, 30, 33, 35, 36, 37 ¼ Lansoprazole is indicated in combination with amoxicillin plus clarithromycin for the treatment of duodenal ulcer associated with H. pylori infection 36, 37.

Lansoprazole also is indicated in combination with amoxicillin in patients who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected 36, 37.

Eradication of H. pylori has been shown to reduce the risk of ulcer recurrence 36, 37.

Hypersecretory conditions, gastric (treatment) 1, 5, 18 ¼ Lansoprazole is indicated for the long-term treatment of pathological hypersecretory conditions 1, 5, 18, 36, 37, including Zollinger-Ellison syndrome 1, 3, 4, 5, 6, 17, 18, 19, 20, 21, 36, 37.

Precautions to Consider

Carcinogenicity

In 2-year studies in rats receiving up to 40 times the recommended human dose, lansoprazole produced dose-related gastric enterochromaffin-like (ECL) cell hyperplasia and ECL cell carcinoids in both male and female rats 1.

Lansoprazole also increased the incidence of intestinal metaplasia of the gastric epithelium, and produced dose-related increases in the incidence of testicular interstitial adenomas 1.

In a 1-year toxicity study in rats receiving 13 times the recommended human dose, testicular interstitial cell adenoma also occurred in 1 of 30 rats 1.

In a 2-year study in mice receiving up to 80 times the recommended human dose, lansoprazole produced an increased incidence of liver tumors (hepatocellular adenomas and carcinomas), a dose-related increase in the incidence of gastric ECL cell hyperplasia, and adenomas of the rete testis in males 1.

Mutagenicity

Lansoprazole was not genotoxic in the Ames test, the ex vivo rat hepatocyte unscheduled DNA synthesis (UDS) test, the in vivo mouse micronucleus test, or the rat bone marrow cell chromosomal aberration test 1.

It was positive in in vitro human lymphocyte chromosomal aberration assays 1.

Pregnancy/Reproduction

Fertility/Reproduction studies in rats and rabbits have shown no evidence of impaired fertility 1.

Pregnancy/Adequate and well-controlled studies in humans have not been done 1.

Reproductive studies in rats and rabbits at doses 40 times the recommended human dose have not shown that lansoprazole causes adverse effects in the fetus 1.

FDA Pregnancy Category B 1.

Breast-feeding

It is not known whether lansoprazole is distributed into breast milk 1.

However, lansoprazole or its metabolites are distributed into the milk of rats 1.

Because lansoprazole has been shown to cause tumorigenic effects in animals, a decision should be made as to whether nursing should be discontinued or the medication withdrawn, taking into account the importance of lansoprazole to the mother 1.

Pediatrics

No information is available on the relationship of age to the effects of lansoprazole in pediatric patients up to 18 years of age. Safety and efficacy have not been established 1.

Geriatrics

Studies in elderly patients indicate that the clearance of lansoprazole is decreased in the elderly 1, 3, 4, 6, 10, resulting in a 50 to 100% increase in the elimination half-life 1.

Because the mean half-life in the elderly remains between 1.9 and 2.9 hours 1, 3, 4, 6, 10, 11, 12, 18, 30, repeated once-daily dosing does not result in accumulation of lansoprazole 1, 6, 11, 30.

However, subsequent doses higher than 30 mg a day should not be administered unless additional gastric acid suppression is necessary 1.