VANZOLE CAPSULES

Lansoprazole Enteric-Coated Granules
30 mg | Pack size: 2 x 7 capsules

DOSAGE AND ADMINISTRATION

Adults: Benign gastric ulcer: 30 mg once daily for up to 8 weeks. NSAID-associated gastric ulcer healing: 30 mg once daily for 8 weeks. Erosive oesophagitis: 30 mg once daily for up to 8 weeks. H. pylori triple therapy: lansoprazole 30 mg twice daily with amoxicillin 1 g and clarithromycin 500 mg twice daily for 10 or 14 days where clinically appropriate and in accordance with resistance guidance. Other indications may require 15 mg or different regimens. Zollinger-Ellison syndrome often starts at 60 mg daily and is individualized by a specialist.

DRUG INTERACTIONS

Lansoprazole may alter absorption of medicines dependent on gastric acidity, including certain antifungals and antiretrovirals. Avoid rilpivirine-containing products. Consider interactions with methotrexate (especially high doses), warfarin, digoxin and tacrolimus. Rifampicin and St John's wort may reduce exposure. Review all medicines, including non-prescription products.

STORAGE

Store according to the approved Vanzole product label, in the original packaging, protected from moisture. Keep out of reach of children. Do not use after expiry.

COMPOSITION

Each capsule contains enteric-coated granules of Lansoprazole equivalent to 30 mg lansoprazole. Excipients: according to the approved Vanzole formulation.

ADMINISTRATION

Take before eating. Swallow capsule whole with water; do not crush or chew the enteric-coated granules. Where the approved capsule instructions permit, it may be opened and intact granules sprinkled onto specified soft food or administered by an approved method; never chew granules. If a dose is missed, take it when remembered unless almost time for the next dose; do not double.

WARNINGS AND PRECAUTIONS

Improvement of symptoms does not exclude gastric malignancy. Investigate alarm features such as persistent vomiting, dysphagia, gastrointestinal bleeding, unexplained weight loss or anaemia. Acute tubulointerstitial nephritis, severe skin reactions and cutaneous or systemic lupus erythematosus have been reported. Persistent diarrhoea may indicate Clostridioides difficile infection.

OVERDOSAGE

Seek urgent medical advice after suspected overdose. Management is supportive and symptom-directed; no specific antidote is established.

THERAPEUTIC CLASS

Proton pump inhibitor (PPI); gastric acid-suppressing medicine.

INDICATIONS

Treatment of active duodenal ulcer; H. pylori eradication in combination with appropriate antibiotics; active benign gastric ulcer; healing of NSAID-associated gastric ulcer; erosive oesophagitis associated with gastro-oesophageal reflux disease (GERD); and pathological hypersecretory conditions including Zollinger-Ellison syndrome. Some maintenance and prevention indications require a 15 mg strength or an individually approved regimen.

LONG-TERM USE

Prolonged PPI treatment may be associated with hypomagnesaemia, vitamin B12 deficiency, bone fractures, fundic gland polyps and other complications. Use the lowest effective dose for the shortest appropriate duration and periodically review continued need.

ADVERSE REACTIONS

Common reactions include headache, diarrhoea, abdominal pain, nausea, constipation and dizziness. Serious reactions may include severe hypersensitivity, kidney inflammation, severe skin reactions, low magnesium and persistent infectious diarrhoea. Seek medical help for severe rash, facial swelling or breathing difficulty.

DESCRIPTION AND PHARMACOLOGY

Lansoprazole inhibits the H+/K+-ATPase proton pump in gastric parietal cells, reducing basal and stimulated acid secretion. Enteric-coated granules protect the acid-labile drug from degradation in the stomach and release it in the intestine.

SPECIAL POPULATIONS

In severe hepatic impairment, consider dosage reduction and monitoring in accordance with the approved product information. Paediatric doses depend on age, body weight and indication; a 30 mg capsule is not suitable for every child. Use only under medical advice.

CONTRAINDICATIONS

Known hypersensitivity to lansoprazole, substituted benzimidazoles or any formulation component. Concomitant use with rilpivirine-containing medicines is contraindicated.

PREGNANCY AND LACTATION

Use during pregnancy only after assessment of expected benefit and potential risk. Information on excretion in human milk is limited; weigh the need for treatment against potential risk to the breastfed infant.

PRESENTATION

Vanzole Capsules 30 mg: 2 x 7 capsules containing enteric-coated lansoprazole granules.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.