V-Es CAPSULES

Esomeprazole 20 mg and 40 mg

Oral delayed-release capsules | 2 x 7 capsules

INDICATIONS

Treatment of gastro-oesophageal reflux disease (GERD), including erosive oesophagitis; maintenance of healed erosive oesophagitis; reduction of NSAID-associated gastric ulcer risk in appropriate patients; as part of combination antibiotic treatment for Helicobacter pylori eradication where approved; and pathological hypersecretory conditions including Zollinger-Ellison syndrome.

CONTRAINDICATIONS

Known hypersensitivity to esomeprazole, other substituted benzimidazoles or formulation components. Concomitant use with rilpivirine-containing products is contraindicated.

PREGNANCY AND LACTATION

Use during pregnancy only after clinical assessment of expected benefit and possible risk. Limited data are available for esomeprazole in breast milk; consider the need for treatment and potential effects on the infant. Consult the prescriber before use.

PRESENTATION

V-Es Capsules 20 mg: 2 x 7 capsules. V-Es Capsules 40 mg: 2 x 7 capsules.

COMPOSITION

Each 20 mg capsule contains esomeprazole (as an appropriate approved salt) equivalent to 20 mg esomeprazole. Each 40 mg capsule contains esomeprazole equivalent to 40 mg esomeprazole. Excipients and exact salt form are as per the approved V-Es formulation.

SPECIAL POPULATIONS

In severe hepatic impairment (Child-Pugh C), the maximum usual dose for GERD-related indications is 20 mg daily; specialist regimens for hypersecretory conditions may differ. Dose selection in children depends on age, weight, indication and local approval. Not all strengths or indications are approved for every pediatric age group.

LONG-TERM THERAPY

Prolonged or high-dose PPI therapy may be associated with low magnesium, vitamin B12 deficiency, bone fractures and fundic gland polyps. Use the lowest effective dose for the shortest appropriate duration; periodically review the indication for continued therapy.

ADVERSE REACTIONS

Common reactions include headache, abdominal pain, diarrhea, nausea, flatulence and constipation. Less common or serious reactions include allergic reactions, low magnesium, kidney inflammation, severe skin reactions and persistent diarrhea. Stop treatment and seek urgent help for facial swelling, breathing difficulty or severe rash.

DESCRIPTION AND CLASS

Esomeprazole is a proton pump inhibitor (PPI) that suppresses gastric acid secretion. This leaflet assumes gastro-resistant/delayed-release capsules; confirm V-Es dosage-form specifications.

METHOD OF USE

Take as prescribed, generally at least one hour before meals for formulations with this labeled requirement. Swallow capsules whole with water. Do not crush or chew enteric-coated granules. Some approved delayed-release capsules may be opened and granules mixed with suitable soft food; use this method only if permitted by the V-Es product specification.

WARNINGS AND PRECAUTIONS

Symptom relief does not exclude gastric malignancy. Evaluate alarm symptoms such as unexplained weight loss, recurrent vomiting, swallowing difficulty, gastrointestinal bleeding or anemia. Acute tubulointerstitial nephritis, severe cutaneous adverse reactions and cutaneous/systemic lupus have been reported. Persistent or severe diarrhea may indicate Clostridioides difficile infection.

OVERDOSAGE

Seek medical advice immediately after suspected overdose. Treatment is supportive and symptom-directed; there is no specific antidote.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.

PHARMACOLOGY

Esomeprazole, the S-isomer of omeprazole, inhibits the gastric parietal-cell H+/K+-ATPase enzyme, reducing basal and stimulated acid secretion.

DOSAGE AND ADMINISTRATION

Adults: Symptomatic GERD: 20 mg once daily for 4 weeks; an additional 4 weeks may be considered. Healing erosive oesophagitis: 20–40 mg once daily for 4–8 weeks. Maintenance after healing: 20 mg once daily. NSAID-associated ulcer risk reduction: 20–40 mg once daily, according to clinical need. Zollinger-Ellison syndrome: generally starts at 40 mg twice daily and is individualized by a specialist. For H. pylori, use only as part of an approved multidrug regimen.

DRUG INTERACTIONS

Avoid concomitant clopidogrel where possible because esomeprazole may reduce its antiplatelet activation. Esomeprazole can affect drugs dependent on gastric pH for absorption (including certain antiretrovirals, antifungals and iron preparations). Monitor interactions with warfarin, digoxin, methotrexate (especially high-dose), tacrolimus and medicines metabolized by CYP2C19. Rifampin and St John's wort may reduce esomeprazole exposure.

STORAGE

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