VAPRA CAPSULES

Omeprazole 20 mg
Oral capsules | Pack size: 2 x 7

COMPOSITION

Each capsule contains Omeprazole 20 mg. Excipients and the exact capsule/pellet formulation are as per the approved Vapra product specification.

THERAPEUTIC CLASS

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

PHARMACOLOGY

Omeprazole suppresses gastric acid secretion by inhibiting the H+/K+-ATPase enzyme (proton pump) in gastric parietal cells. Acid-resistant delayed-release formulations protect omeprazole from degradation by stomach acid.

INDICATIONS

Treatment of active duodenal ulcer; eradication of Helicobacter pylori as part of appropriate combination therapy; active benign gastric ulcer; symptomatic gastro-oesophageal reflux disease (GERD); erosive oesophagitis due to acid-mediated GERD and maintenance of healing; and pathological hypersecretory conditions, including Zollinger-Ellison syndrome, according to approved indications.

DOSAGE AND ADMINISTRATION

Adults: Active duodenal ulcer: 20 mg once daily for 4 weeks; some patients require another 4 weeks. Symptomatic GERD: 20 mg once daily for up to 4 weeks. Erosive oesophagitis: 20 mg once daily for 4–8 weeks. Maintenance after healing: 20 mg once daily. Active benign gastric ulcer: commonly 40 mg once daily for 4–8 weeks (requires two 20 mg capsules or an appropriate strength). Hypersecretory conditions: starting dose commonly 60 mg daily, adjusted by a specialist.

H. PYLORI ERADICATION

Use only with an appropriate antibiotic regimen based on local guidance and resistance patterns. An established triple-therapy regimen is omeprazole 20 mg, amoxicillin 1 g and clarithromycin 500 mg, each twice daily for 10 days; current local treatment guidance may prefer alternative regimens. Never use omeprazole alone for eradication.

METHOD OF ADMINISTRATION

Take before meals as directed. Swallow the capsule whole with water; do not crush or chew enteric-coated pellets. Some approved delayed-release capsules may be opened and intact pellets sprinkled onto applesauce for immediate swallowing; follow Vapra-specific instructions before doing so. If a dose is missed, take it when remembered unless the next dose is due; do not double doses.

CONTRAINDICATIONS

Known hypersensitivity to omeprazole, substituted benzimidazoles or any component of the formulation. Concomitant use with rilpivirine-containing products is contraindicated. Check additional contraindications when antibiotics are prescribed for H. pylori.

WARNINGS AND PRECAUTIONS

Symptom improvement does not exclude gastric malignancy. Investigate alarm symptoms such as difficulty swallowing, persistent vomiting, unexplained weight loss, anaemia or gastrointestinal bleeding. Acute tubulointerstitial nephritis, severe cutaneous adverse reactions, cutaneous or systemic lupus and Clostridioides difficile-associated diarrhoea have been reported with PPIs.

LONG-TERM USE

Use the lowest effective dose for the shortest appropriate duration. Prolonged or multiple-daily-dose PPI use may be associated with hypomagnesaemia, vitamin B12 deficiency, increased fracture risk and fundic gland polyps. Reassess the need for continued treatment periodically.

DRUG INTERACTIONS

Avoid concomitant clopidogrel where possible because omeprazole may reduce formation of its active metabolite. Do not combine with rilpivirine. Omeprazole may affect absorption of drugs requiring acidic gastric pH and may interact with warfarin, phenytoin, diazepam, digoxin, tacrolimus, high-dose methotrexate and certain antiretrovirals. Rifampicin and St John's wort may reduce omeprazole exposure.

PREGNANCY AND LACTATION

Use in pregnancy only following clinical assessment of the benefits and risks. Omeprazole is present in human milk; consider the need for treatment and potential effects on the breastfed infant.

PAEDIATRIC AND SPECIAL POPULATIONS

Paediatric use and dosing depend on age, weight and indication; the 20 mg capsule is not suitable for all children. Dose adjustment may be required in hepatic impairment for maintenance therapy. Follow the approved product information and specialist advice.

ADVERSE REACTIONS

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

OVERDOSAGE

Seek medical attention if overdose is suspected. Treatment is supportive and symptom-directed; no specific antidote is established.

STORAGE

Store in the original packaging according to Vapra's approved storage conditions, protected from moisture. Keep out of reach of children. Do not use after expiry.

PRESENTATION

Vapra Capsules 20 mg: 2 x 7 capsules.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.