OME-US

Omeprazole Powder For Oral Suspension 10mg/5 ml

Composition:
Each 5 ml of reconstituted suspension contains:
Omeprazole USP……10 mg
Excipients ……..q.s
Approved colour used.

Pharmaceutical Form:
Powder for Oral Suspension, after reconstitution.

Therapeutic indications:
Omeprazole Powder for Oral Suspension is indicated for:
- Helicobacter pylori eradication [in combination with other drugs].
- Benign gastric ulceration.
- Duodenal ulceration.
- Prevention of relapse in gastric and duodenal ulcer.
- NSAID-associated duodenal ulcer, gastric ulcer, gastroduodenal erosions
- Prophylaxis in patients with a history of NSAID-associated duodenal ulcer, gastric ulcer, gastroduodenal lesions and dyspeptic symptoms who require continued NSAID treatment.
- Zollinger–Ellison syndrome.
- Gastro-oesophageal reflux disease.
- Severe oesophagitis.
- Severe oesophagitis, refractory to initial treatment.
- Acid reflux disease (long-term management).
- Functional dyspepsia.
- Uninvestigated dyspepsia.

Posology and method of administration:
Posology:
Helicobacter pylori eradication [in combination with other drugs]:
Adult: 10–40 mg twice daily for 7 days for first- and second-line eradication therapy; 10 days for third-line eradication therapy.
Benign gastric ulceration, Duodenal ulceration:
Adult: 10 mg once daily for 8 weeks & for 4 weeks respectively, increased if necessary to 40 mg once daily, in severe or recurrent cases.
Prevention of relapse in gastric ulcer
Adult: 10 mg once daily, increased if necessary to 40 mg once daily.
revention of relapse in duodenal ulcer:
Adult: 10 mg once daily, dose may range between 10–40 mg daily.
NSAID-associated duodenal ulcer, gastric ulcer, gastroduodenal erosions:
Adult: 10 mg once daily for 4 weeks, continued for a further 4 weeks if not fully healed.
Prophylaxis in patients with a history of NSAID-associated duodenal ulcer, gastric ulcer, gastroduodenal lesions and dyspeptic symptoms who require continued NSAID treatment:
Adult: 10 mg once daily.
Zollinger–Ellison syndrome:
Adult: Initially 60 mg once daily; usual dose 10–120 mg daily, total daily doses greater than 80mg should be given in 2 divided doses.
Gastro-oesophageal reflux disease:
Adult: 10 mg once daily for 4 or 8 weeks.
Severe oesophagitis:
Adult: 40 mg once daily for 8 weeks, continue as maintenance treatment if appropriate.
Severe oesophagitis, refractory to initial treatment:
Adult: 40 mg twice daily.
Acid reflux disease (long-term management):
Adult: 10 mg once daily, increased if necessary up to 40 mg once daily, dose only increased if symptoms return.
Functional dyspepsia and Uninvestigated dyspepsia:
Adult: 10 mg and 10 mg once daily for 4 weeks respectively.

Method of administration:
For oral administration, after reconstitution.
SHAKE WELL BEFORE USE.

Preparation of recostituted suspension:
Shake the bottle well to loosen the powder. Add boiled & cooled water to constitute the powder upto the mark shown on the bottle. The mixture needs to be shaken vigorously until all the powder has disappeared from the bottom and suspension is formed. It may be necessary to readjust the volume up to the mark.

Contraindications:
Hypersensitivity to the active substance, substituted benzimidazoles or to any of the excipients of the formulation.
Omeprazole like other proton pump inhibitors (PPIs) must not be used concomitantly with nelfinavir.

Warnings and Precautions:
In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment may alleviate symptoms and delay diagnosis.
Co-administration of atazanavir with proton pump inhibitors is not recommended.
Omeprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy.
Omeprazole is a CYP2C19 inhibitor. When starting or ending treatment with omeprazole, the potential for interactions with drugs metabolised through CYP2C19 should be considered. An interaction is observed between clopidogrel and omeprazole.
Severe hypomagnesaemia has been reported in patients treated with proton pump inhibitors (PPIs) like omeprazole for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked.
For patients expected to be on prolonged treatment or who take PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g. diuretics), healthcare professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.
Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors.
Renal impairment:
Acute tubulointerstitial nephritis (TIN) has been observed in patients taking omeprazole and may occur at any point during omeprazole therapy. Acute tubulointerstitial nephritis can progress to renal failure.
Subacute cutaneous lupus erythematosus (SCLE):
Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping Omeprazole. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

Drug interactions:
Effects of omeprazole on the pharmacokinetics of other active substances:
Active substances with pH dependent absorption:
The decreased intragastric acidity during treatment with omeprazole might increase or decrease the absorption of active substances with a gastric pH dependent absorption.
Nelfinavir, atazanavir
The plasma levels of nelfinavir and atazanavir are decreased in case of co-administration with omeprazole.
Concomitant administration of omeprazole with nelfinavir is contraindicated.
Concomitant administration of omeprazole with atazanavir is not recommended.
Digoxin:
Concomitant treatment with omeprazole (10 mg daily) and digoxin in healthy subjects increased the bioavailability of digoxin by 10%.
Clopidogrel:
Results from studies in healthy subjects have shown a pharmacokinetic (PK)/pharmacodynamic (PD) interaction between clopidogrel (300 mg loading dose/75 mg daily maintenance dose) and omeprazole (80 mg p.o. daily) resulting in a decreased exposure to the active metabolite of clopidogrel by an average of 46% and a decreased maximum inhibition of (ADP induced) platelet aggregation by an average of 16%.
Other active substances:
The absorption of posaconazole, erlotinib, ketoconazole and itraconazole is significantly reduced and thus clinical efficacy may be impaired.
Active substances metabolised by CYP2C19:
Omeprazole is a moderate inhibitor of CYP2C19, the major omeprazole metabolising enzyme. Thus, the metabolism of concomitant active substances also metabolised by CYP2C19, may be decreased and the systemic exposure to these substances increased. Examples of such drugs are R-warfarin and other vitamin K antagonists, cilostazol, diazepam and phenytoin.
Cilostazol:
Omeprazole, given in doses of 40 mg to healthy subjects in a cross-over study, increased Cmax and AUC for cilostazol by 18% and 26% respectively, and one of its active metabolites by 29% and 69% respectively.
Phenytoin:
Monitoring phenytoin plasma concentration is recommended during the first two weeks after initiating omeprazole treatment.
Unknown mechanism:
Saquinavir:
Concomitant administration of omeprazole with saquinavir/ritonavir resulted in increased plasma levels up to approximately 70% for saquinavir associated with good tolerability in HIV-infected patients.
Tacrolimus:
Concomitant administration of omeprazole has been reported to increase the serum levels of tacrolimus.
Methotrexate:
When given together with proton-pump inhibitors, methotrexate levels have been reported to increase in some patients.
Effects of other active substances on the pharmacokinetics of omeprazole
Inhibitors CYP2C19 and/or CYP3A4:
Since omeprazole is metabolised by CYP2C19 and CYP3A4, active substances known to inhibit CYP2C19 or CYP3A4 (such as clarithromycin and voriconazole) may lead to increased omeprazole serum levels by decreasing omeprazole's rate of metabolism. Concomitant voriconazole treatment resulted in more than doubling of the omeprazole exposure.
Inducers of CYP2C19 and/or CYP3A4:
Active substances known to induce CYP2C19 or CYP3A4 or both (such as rifampicin and St John's wort) may lead to decreased omeprazole serum levels by increasing omeprazole's rate of metabolism.
Pregnancy and Lactation:
Pregnancy:
Results from three prospective epidemiological studies (more than 1000 exposed outcomes) indicate no adverse effects of omeprazole on pregnancy or on the health of the foetus/newborn child. Omeprazole can be used during pregnancy.
Lactation:
Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

Undesirable effects:
Rare or very rare:
- aggression
- agitation
- bronchospasm
- encephalopathy
- gastrointestinal candidiasis
- muscle weakness

Overdose:
Nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache have been reported. Also apathy, depression and confusion have been described in single cases.
The symptoms described have been transient, and no serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses. Treatment, if needed, is symptomatic.

Storage:
Dry powder: Store below 25°C. Protect from light and moisture.

Reconstituted Suspension: Should be stored in a refrigerator (2°C - 8°C) for 14 days.
Store in the original container in order to protect from light. Keep the bottle tightly closed.

Keep medicines out of reach of children.

Presentation:
150 ml amber glass bottle packed in a printed carton and measuring cup.

MOH, Kuwait

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