Bosch

For Medical Professional only

Omezol® INJECTION

(O m e p r a z o l e)

اومیزول انجکشن

(اومیپرازول)

DESCRIPTION:
Omezol (omeprazole) is a substituted benzimidazole, 5-methoxy-2¬ [[(4-methoxy-3, 5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1H-benzimidazole, a compound that inhibits gastric acid secretion. Its empirical formula is $C_{17}H_{19}N_3O_3S$, with a molecular weight of 345.42.

COMPOSITION:
Each vial contains :
Omeprazole.....40mg as Omeprazole Sodium B.P.
(Product Specs.: Innovator's)

CLINICAL PHARMACOLOGY:
Pharmacodynamic Properties:
Pharmacotherapeutic group: Proton pump inhibitors, ATC code: A02BC01

Mechanism of Action:
Omeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H+,K+-ATPase - the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for highly effective inhibition of both basal acid secretion and stimulated acid secretion, irrespective of stimulus.

THERAPEUTIC INDICATIONS:
Omeprazole 40 mg powder for solution for infusion for intravenous use is indicated as an alternative to oral therapy for the following indications i.e.
- Treatment and Prevention of duodenal, gastric ulcers, and its relapse
- In combination with appropriate antibiotics, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease
- Treatment and Prevention of NSAID-associated gastric and duodenal ulcers
- Treatment and Long-term management of patients with reflux esophagitis
- Treatment of symptomatic gastro-esophageal reflux disease and Zollinger-Ellison syndrome

DOSAGE AND ADMINISTRATION:
Alternative to oral therapy
In patients where the use of oral medicinal products is inappropriate, Omeprazol 40 mg powder for solution for infusion IV 40 mg once daily is recommended. In patients with Zollinger-Ellison Syndrome the recommended initial dose of Omeprazol 40 mg powder for solution for infusion given intravenously is 60 mg daily. Higher daily doses may be required and the dose should be adjusted individually. When doses exceed 60 mg daily, the dose should be divided and given twice daily.

Method of Administration:
For IV injection
Reconstitute Omeprazole IV with 10mL sterile water for injection to make a 10mL solution containing 4mg/mL omeprazole approximately. After reconstitution, Omeprazole IV should be given as intravenous injection, slowly over a period of atleast 2.5 minutes at a maximum rate of 4mL/min. The reconstituted solution is stable for approximately 8 hours when stored in the original vial in a cool place.

For IV Infusion:
For IV infusion, add the 10mL reconstituted solution to 90mL of 0.9% w/v of sodium chloride solution for injection or 5% w/v of dextrose solution for injection in I.V. bag to make 100mL solution containing 0.4mg/mL of omeprazole approximately. Each infusion once prepared should be used immediately. Omeprazol 40 mg powder for solution for infusion is to be administered in an intravenous infusion for 20-30 minutes. An infusion prepared in 5% dextrose has a shelf life of 6 hours, while an infusion prepared in normal saline has a shelf life of 12 hours.

CONTRAINDICATIONS:
Hypersensitivity to omeprazole, substituted benzimidazoles or to any of the excipients.
Omeprazole like other proton pump inhibitors (PPIs) should not be used concomitantly with nelfinavir.

WARNINGS AND PRECAUTIONS:
In the presence of any alarm symptoms (eg, 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 B^{12} (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B^{12} 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. The clinical relevance of this interaction is uncertain. As a precaution, concomitant use of omeprazole and clopidogrel should be avoided.

Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.
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. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI.

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.

Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium. Interference with laboratory test results.

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.

DRUG INTERACTIONS:
The decreased intragastric acidity during treatment with omeprazole might increase or decrease the absorption of active substances with a gastric pH dependent absorption.

The plasma levels of nelfinavir and atazanavir are decreased in case of co-administration with omeprazole is contraindicated.

Digoxin
Concomitant treatment with omeprazole (20 mg daily) and digoxin in healthy subjects increased the bioavailability of digoxin by 10%. Digoxin toxicity has been rarely reported. However caution should be exercised when omeprazole is given at high doses in elderly patients. Therapeutic drug monitoring of digoxin should be then be reinforced.

Clopidogrel
As precaution, concomitant use of omeprazole and clopidogrel should be discouraged.
Other active substances
The absorption of posaconazole, erlotinib, ketoconazol and itraconazol is significantly reduced and thus clinical efficacy may be impaired. For posaconazol and erlotinib concomitant use should be avoided.

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.

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 and, if a phenytoin dose adjustment is made, monitoring and a further dose adjustment should occur upon ending omeprazole treatment.

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. In high-dose methotrexate administration a temporary withdrawal of omeprazole may need to be considered.

CYP2C19 and/or CYP3A4
Inhibitors may lead to increased omeprazole serum levels by decreasing omeprazole's rate of metabolism and Inducers may lead to decreased omeprazole serum levels by increasing omeprazole's rate of metabolism.

ADVERSE EFFECTS:
Common:
Headache, Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, fundic gland polyps (benign)

Uncommon:
Insomnia, Dizziness, paraesthesia, somnolence, Vertigo, Increased liver enzymes, Dermatitis, pruritus, rash, urticaria, Fracture of the hip, wrist or spine, Malaise, peripheral oedema.

Rare:
Leukopenia, thrombocytopenia, Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock, Hyponatraemia, Agitation, confusion, depression, Taste disturbance, Blurred vision, Bronchospasm, Dry mouth, stomatitis, gastrointestinal candidiasis, Hepatitis with or without jaundice, Alopecia, photosensitivity, Arthralgia, myalgia, Interstitial nephritis, Increased sweating.

Very Rare:
Agranulocytosis, pancytopenia, Aggression, hallucinations, Hepatic failure, encephalopathy in patients with pre-existing liver disease, Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), Muscular weakness, Gynaecomastia.

Not Known:
Hypomagnesaemia; severe hypomagnesaemia may result in hypocalcaemia, Hypomagnesaemia may also be associated with hypokalaemia, Microscopic colitis, Subacute cutaneous lupus erythematosus

USE IN PREGNANCY AND LACTATION:
Pregnancy:
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.

OVERDOSE:
No serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses. Treatment, if needed, is symptomatic.

INCOMPATIBILITIES:
This medicinal product should not be mixed with other medicinal products

SHELF LIFE:
2 years.

INSTRUCTIONS:
Protect from light & moisture, store below 25°C.
Keep out of reach of the children.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

PRESENTATION:
Omezol (Omeprazole) I.V. 40 mg is a lyophilized powder for IV Infusion/Injection available as one vial per pack with 1 ampoule (10ml) of sterile Water for Injection as diluent.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:-
صرف وریدی استعمال کے لئے۔
دھوپ، گرمی اور نمی سے محفوظ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دُور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
Bosch Pharmaceuticals (Pvt) Ltd.
209, Sector 23, Korangi Industrial Area,
Karachi - Pakistan.
For **Bosch Pharmaceuticals (Pvt.) Ltd.**
221-223, Sector 23, K.I.A. Karachi-Pakistan.

ISO 9001:2015 Certified Company