Bharat Parenterals Limited
Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

MEGASTROLE 40 INJ - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

Generic Name/INN Name: Omeprazole for Injection 40 mg

Trade Name: MEGASTROLE 40 INJ

Strength:

Each vial contains:
Omeprazole Sodium BP eq. to
Omeprazole 40 mg

2. Qualitative and Quantitative composition:

Sr. No	Ingredients	Spec	Label claim (mg/Vial)	Std. Qty. mg/Vial	Function
1.	Sterile Omeprazole Sodium (Lyophilized) equivalent to Omeprazole*	BP	40.00 mg	123.00 mg	Active

* Add the calculated quantity based on the Assay (potency) and Water content of sterile Omeprazole Sodium BP.

3. Pharmaceutical form:

Dosage Form: Powder for Injection

Visual & Physical characteristics of the product: A white or almost white, hygroscopic powder filled in intactly sealed Amber glass vial.

4. Clinical particulars

4.1. Therapeutic indications:

As alternative treatment of the oral formulation where fast and pronounced acidity inhibition is required for:

Duodenal ulcer

Benign gastric ulcer

Reflux oesophagitis

Zollinger-Ellison syndrome

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4.2. Posology and method of administration:

Dosage

Route of administration: I.V. use.

Omeprazole 40 mg as once daily intravenous application is only recommended in those incidental cases where oral therapy is inappropriate and pronounced acidity inhibition is essential. The mean reduction of acid production in the stomach during 24 hours is circa 90%. With Zollinger-Ellison patients the recommended initial dosage is 60 mg Omeprazole per day. For a 60 mg dose an additional half (5 ml) of the reconstituted solution should be given as an intravenous injection. Any unused solution should be discarded. Higher dosages can be necessary and the dosage should be individually adjusted. With a total dosage of more than 60 mg per day the administration of the daily dosage should be spread out over the day. A one week treatment is usually sufficient.

Reduced renal or hepatic function

The dosage does not need to be adjusted for renal function. In patients with hepatic function disorders the biological availability can be enhanced and the plasma half-life of Omeprazole can increase. In these patients a daily dosage of 10-20 mg can be sufficient.

Children

There is limited experience of use in children. Therefore Omeprazole injection is not recommended in children.

The elderly

Omeprazole can be administered to the elderly without adjustment of the dosage.

Method of administration:

Omeprazole injection solution may only be administered as an intravenous injection. The solution must not be added to an infusion solution. After preparation the injection must be administered slowly with a maximum speed of 2 ml/minute (over a period of at least 5 minutes, or 2.5 minutes when half of the reconstituted solution is given). After reconstitution, the preparation should be used within 4 hours and any unused portion should be discarded.

4.3. Contraindications:

Omeprazole is contraindicated in patients with hypersensitivity to Omeprazole.

Omeprazole like other proton pump inhibitors should not be administered with Atazanavir.

4.4. Special warnings and precautions for use:

In patients with peptic ulcer disease Helicobacter pylori-status should be determined if relevant. In patients who are shown to be Helicobacter pylori-positive, the elimination of the bacterium by eradication therapy should be aimed wherever possible.

In the presence of any alarm symptoms (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia haematemesis or melaena) and when gastric ulcer is suspected, the possibility of malignancy must be excluded before treatment with Omeprazole is instituted, as treatment may alleviate symptoms and delay diagnosis.

The diagnosis of reflux oesophagitis should be confirmed endoscopically.

Decreased gastric acidity, due to any means – including proton-pump inhibitors – increases gastric counts of bacteria normally present in the gastro-intestinal tract. Treatment with acid-reducing medicinal products leads to a slightly increased risk of gastrointestinal infections, such as Salmonella and Campylobacter.

In patients with severe impaired hepatic function, liver enzyme values should be checked periodically during treatment with Omeprazole.

During combination treatment caution should also be exercised in patients with severe renal and hepatic dysfunction.

Blindness and deafness have been reported in the use of the injection form of Omeprazole; therefore, in severely ill patients the monitoring of visual and auditory senses is recommended.

This medicinal product is essentially 'sodium- free'. The total amount of sodium (Na+) in the reconstituted solution is less than 1 mmol (23 mg) per 40 mg dose.

4.5. Interaction with other medicinal products and other forms of interaction:

As Omeprazole is metabolised in the liver through cytochrome P450 isoforms (mainly CYP 2C19, S-mephenytoin hydroxylase) and inhibits enzymes of the CYP2C subfamily (CYP 2C19 and CYP 2C9) it can delay the elimination of other active substances metabolised by

these enzymes. This has been observed for diazepam (and also of other benzodiazepines as triazolam or flurazepam), phenytoin and warfarin.

In patients under continuous treatment with phenytoin, the concomitant treatment with 20 mg daily of Omeprazole orally did not modify the phenytoin plasma concentration. In the same way, the concomitant treatment with 20 mg daily of Omeprazole orally did not cause a modification in the coagulation time in patients under continuous treatment with warfarin. Periodic monitoring of patients receiving warfarin or phenytoin is recommended and a reduction of warfarin or phenytoin dose may be necessary.

Other active substances that could be affected are hexabarbital, citalopram, imipramine, clomipramine etc.

Omeprazole may inhibit the hepatic metabolism of disulfiram. After concomitant oral use, some possibly related cases of muscular rigidity have been reported.

There are contradictionary data on the interaction of orally administered Omeprazole with ciclosporin. Therefore, the plasma levels of ciclosporin should be monitored in those patients treated with Omeprazole, because an increase in ciclosporin levels is possible.

Plasma concentrations of Omeprazole and clarithromycin are increased during concomitant oral administration. Although, there is no interaction with metronidazole or amoxicillin, these antimicrobial agents are used concomitantly with Omeprazole in order to eradicate Helicobacter pylori.

Due to the decreased intragastric acidity, the absorption of ketoconazole or itraconazole may be reduced during Omeprazole treatment as it is with other acid secretion inhibitors and antacids.

Simultaneous treatment with Omeprazole and digoxin in healthy subjects lead to a 10 % increase in the bioavailability of digoxin as a consequence of the increased gastric pH.

Co-administration of Omeprazole (40 mg once daily) with atazanavir 300 mg/ritonavir 100 mg to healthy volunteers resulted in a substantial reduction in atazanavir exposure (approximately 75% decrease in AUC, Cmax, and Cmin). Increasing the atazanavir dose to 400 mg did not compensate for the impact of Omeprazole on atazanavir exposure. Proton pump inhibitors including Omeprazole should not be co-administered with atazanavir (see section 4.3).

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Omeprazole may reduce the oral absorption of vitamin B12. This should be taken into account in those patients with low basal levels who undergo a long-term treatment with Omeprazole.

Because of potential clinically significant interaction St. John's wort should not be used concomitantly with Omeprazole.

There is no evidence of an interaction with caffeine, propranolol, theophylline, metoprolol, lidocaine, quinidine, phenacetin, estradiol, amoxicillin, budesonide, diclofenac, metronidazole, naproxen, piroxicam, or antacids when Omeprazole is given orally.

4.6. Pregnancy and lactation:

There is limited experience on the use of Omeprazole in pregnant women. Experience to date indicates no increased risk of congenital malformations or other adverse effects of Omeprazole on pregnancy or the unborn child. Animal studies do not indicate direct or indirect harmful effects with respect to reproduction.

Omeprazole Injection should only be prescribed during pregnancy when strictly indicated.

Omeprazole is excreted in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Omeprazole Injection should be made taken into account the benefit of breast-feeding to the child and the benefit of therapy to the woman.

4.7. Effects on ability to drive and use machines:

No studies on the ability to drive and use machines have been performed. However, apart from side effects affecting the CNS or visual abilities, no effects on the ability to drive are expected from the intake of Omeprazole.

4.8. Undesirable effects:

Omeprazole is well tolerated, in general, undesirable effects are mild and reversible. In clinical trials performed and post-authorisation follow up, the following undesirable effects have been notified, although in most cases a casual relationship could not be established between such reactions and Omeprazole treatment. In order to classify them the following frequencies definition have been followed:

- very common (≥1/10)
- common (≥1/100, ≥1/1,000, ≥1/10,000, ≤1/1,000)