Bharat Parenterals Limited
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CIN NO: U24231GJ1992PLC018237

MEGASTROLE 20 - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name:

Omeprazole Capsules

Trade Name: MEGASTROLE-20

1.2 Strength:

Omeprazole BP..... 20 mg (Enteric coated granules)

1.3 Pharmaceutical form:

Solid Oral Dosage form (capsule)

2. Qualitative and Quantitative composition:

Omeprazole BP.....20 mg (as enteric coated granules)

3. Pharmaceutical form:

Dosage Form: Solid Oral Dosage form (Capsules)

Visual & Physical characteristics of the product

A green/ white coloured hard gelatin capsule, size "2" containing white colour enteric coated granules, having symbol " conical flask B" on cap & body.

4. Clinical particulars:

4.1. Therapeutic indications:

In adults:

'Gastro-esophageal reflux disease' (GERD).

Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).

Ulcers which are infected with bacteria called 'Helicobacter pylori'

Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).

In children:

Children over 1 year of age and ≥ 10 kg:

'Gastro-esophageal reflux disease' (GERD).

Children and adolescents over 4 years of age:

Ulcers which are infected with bacteria called 'Helicobacter pylori'.

4.2. Posology and method of administration:

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Dosage:

Adult

To treat symptoms of GERD such as heartburn and acid regurgitation:

The usual dose is 20 mg once a day for 4-8 weeks. A dose of 40 mg for a further 8 weeks if your gullet has not yet healed.

The usual dose once the gullet has healed is 10 mg once a day.

If your gullet has not been damaged, the usual dose is 10 mg once a day.

To treat ulcers in the upper part of the intestine (duodenal ulcer):

The usual dose is 20 mg once a day for 2 weeks. If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat ulcers in the stomach (gastric ulcer):

The usual dose is 20 mg once a day for 4 weeks. If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To prevent the duodenal and stomach ulcers from coming back:

The usual dose is 10 mg or 20 mg once a day.

To treat duodenal and stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

The usual dose is 20 mg once a day for 4-8 weeks.

To prevent duodenal and stomach ulcers if you are taking NSAIDs:

The usual dose is 20 mg once a day.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):

The usual dose is 60 mg daily.

Children:

To treat symptoms of GERD such as heartburn and acid regurgitation:

Children over 1 year of age and with a body weight of more than 10 kg may take Omeprazole.

To treat ulcers caused by Helicobacter pylori infection and to stop them coming back:

Children aged over 4 years may take Omeprazole. The dose for children is based on the child's weight and the doctor will decide the correct dose.

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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 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. If the combination of atazanavir with a proton pump inhibitor is judged unavoidable, close clinical monitoring (e.g virus load) is recommended in combination with an increase in the dose of atazanavir to 400 mg with 100 mg of ritonavir; omeprazole 20 mg should not be exceeded.

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. The clinical relevance of this interaction is uncertain. As a precaution, concomitant use of omeprazole and clopidogrel should be discouraged.

Some children with chronic illnesses may require long-term treatment although it is not recommended.

Hypomagnesaemia

Severe hypomagnesaemia has been reported in patients treated with 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.

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For patients expected to be on prolonged treatment or who take PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g., diuretics), health care 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 recognized risk factors. Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10–40%. Some of this increase may be due to other risk factors. 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.

Omeprazole capsules contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.

As in all long-term treatments, especially when exceeding a treatment period of 1 year, patients should be kept under regular surveillance.

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.

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.