



## **Bharat Parenterals Limited**

Registered Office & Works:  
Vil. 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 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  $\geq 10$  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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**MEGASTROLE-20 (Omeprazole Capsules)**





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### **MEGASTROLE 20 - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

#### **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:**

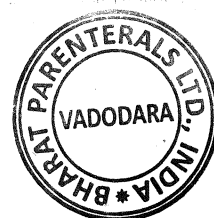
Children over 1 year of age and with a body weight of more than 10 kg may take Omeprazole.

##### **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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### **MEGASTROLE 20 - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

#### **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.

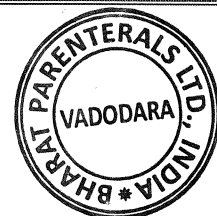
#### **4.5 Interaction with other medicinal products and other forms of interaction:**

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.

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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 contradictory 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.

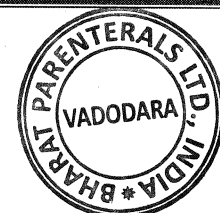
#### **4.6 Pregnancy and lactation:**

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.

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### MEGASTROLE 20 - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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.

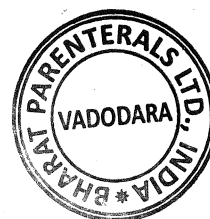
#### 4.7. Effects on ability to drive and use machines:

No studies on the ability to drive and use machines have been performed.

#### 4.8 Undesirable effects:

<b>Blood and the lymphatic system disorders</b>	Rare: leucopenia, thrombocytopenia, agranulocytosis and pancytopenia. Very rare: changes in blood count
<b>Immune system disorders</b>	Uncommon: urticaria. Rare: hypersensitivity reactions e.g. fever, angioedema, bronchospasm and anaphylactic shock, allergic vasculitis.
<b>Nervous system disorders</b>	Common: somnolence, sleep disturbances (insomnia), vertigo, headaches and drowsiness. These complaints usually improve during continued therapy.
<b>Eye disorders</b>	Uncommon: visual disturbances (blurred vision, loss of visual acuity or reduced field of vision). These conditions usually resolve on cessation of therapy.
<b>Ear and labyrinth disorders</b>	Uncommon: auditory dysfunction (e.g. tinnitus). These conditions usually resolve on cessation of therapy.
<b>Gastrointestinal disorders</b>	Common: diarrhoea, constipation, flatulence (possibly with abdominal pain), nausea and vomiting.
<b>Hepato-biliary</b>	Uncommon: increase of liver enzyme values

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### MEGASTROLE 20 - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

<b>disorders</b>	
<b>Skin and subcutaneous tissue disorders:</b>	Uncommon: pruritus, skin eruptions, alopecia, erythema multiforme or photosensitivity and increased tendency to sweat.
<b>Musculoskeletal, connective tissue and bone disorders</b>	Rare: muscle weakness, myalgia and joint pain.
<b>Renal and urinary disorders</b>	Rare: nephritis (interstitial nephritis)
<b>Other adverse effects</b>	Uncommon: malaise, peripheral oedema

In sporadic cases irreversible visual disorders have been reported with very seriously ill patients who were treated with intravenous injections of Omeprazole and then, in particular, with high dosages. A causal link has however not been established.

#### **4.9. Overdose:**

There is limited information available on the effects of overdoses of omeprazole in humans. In the literature, doses of up to 560 mg have been described, and occasional reports have been received when single oral doses have reached up to 2,400 mg omeprazole (120 times the usual recommended clinical dose). 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.

#### **5. Pharmacological properties:**

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### **MEGASTROLE 20 - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

#### **5.1 Pharmacodynamic properties:**

**Pharmacotherapeutic group:** Selective proton pump inhibitor, substituted benzimidazole.

ATC-CODE: A02B C01

#### **Mechanism of action**

Omeprazole, a racemic mixture of two enantiomers reduces gastric acid secretion through a highly targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell. It is rapidly acting and provides control through reversible inhibition of gastric acid secretion with once daily dosing.

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<sup>+</sup> K<sup>+</sup>-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.

#### **Pharmacodynamic effects**

All pharmacodynamic effects observed can be explained by the effect of omeprazole on acid secretion.

#### **Effect on gastric acid secretion**

Oral dosing with omeprazole once daily provides for rapid and effective inhibition of daytime and night time gastric acid secretion with maximum effect being achieved within 4 days of treatment. With omeprazole 20 mg, a mean decrease of at least 80% in 24-hour intragastric acidity is then maintained in duodenal ulcer patients, with the mean decrease in peak acid output after pentagastrin stimulation being about 70% 24 hours after dosing.

Oral dosing with omeprazole 20 mg maintains an intragastric pH of  $\geq 3$  for a mean time of 17 hours of the 24-hour period in duodenal ulcer patients.

As a consequence of reduced acid secretion and intragastric acidity, omeprazole dose-dependently reduces/normalizes acid exposure of the esophagus in patients with gastro-esophageal reflux disease. The inhibition of acid secretion is related to the area under the plasma concentration-time curve (AUC) of omeprazole and not to the actual plasma concentration at a given time.

No tachyphylaxis has been observed during treatment with omeprazole.

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#### Effect on *H. pylori*

*H. pylori* is associated with peptic ulcer disease, including duodenal and gastric ulcer disease. *H. pylori* is a major factor in the development of gastritis. *H. pylori* together with gastric acid are major factors in the development of peptic ulcer disease. *H. pylori* is a major factor in the development of atrophic gastritis which is associated with an increased risk of developing gastric cancer.

Eradication of *H. pylori* with omeprazole and antimicrobials is associated with, high rates of healing and long-term remission of peptic ulcers.

Dual therapies have been tested and found to be less effective than triple therapies. They could, however, be considered in cases where known hypersensitivity precludes use of any triple combination.

#### Other effects related to acid inhibition

During long-term treatment gastric glandular cysts have been reported in a somewhat increased frequency. These changes are a physiological consequence of pronounced inhibition of acid secretion, are benign and appear to be reversible.

Decreased gastric acidity due to any means including proton pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with acid-reducing drugs may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter.

#### Paediatric use

In a non-controlled study in children (1 to 16 years of age) with severe reflux esophagitis, omeprazole at doses of 0.7 to 1.4 mg/kg improved esophagitis level in 90% of the cases and significantly reduced reflux symptoms. In a single-blind study, children aged 0–24 months with clinically diagnosed gastroesophageal reflux disease were treated with 0.5, 1.0 or 1.5 mg omeprazole/kg. The frequency of vomiting/regurgitation episodes decreased by 50% after 8 weeks of treatment irrespective of the dose.

#### **5.2 Pharmacokinetic properties:**

##### **Absorption:**

Omeprazole and omeprazole magnesium are acid labile and are therefore administered orally as enteric-coated granules in capsules or tablets. Absorption of omeprazole is rapid, with

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peak plasma levels occurring approximately 1-2 hours after dose. Absorption of omeprazole takes place in the small intestine and is usually completed within 3-6 hours. Concomitant intake of food has no influence on the bioavailability. The systemic availability (bioavailability) from a single oral dose of omeprazole is approximately 40%. After repeated once-daily administration, the bioavailability increases to about 60%.

#### **Distribution:**

The apparent volume of distribution in healthy subjects is approximately 0.3 l/kg body weight. Omeprazole is 97% plasma protein bound.

#### **Metabolism:**

Omeprazole is completely metabolised by the cytochrome P<sub>450</sub> system (CYP). The major part of its metabolism is dependent on the polymorphically expressed CYP2C19, responsible for the formation of hydroxyomeprazole, the major metabolite in plasma. The remaining part is dependent on another specific isoform, CYP3A4, responsible for the formation of omeprazole sulphone. As a consequence of high affinity of omeprazole to CYP2C19, there is a potential for competitive inhibition and metabolic drug-drug interactions with other substrates for CYP2C19. However, due to low affinity to CYP3A4, omeprazole has no potential to inhibit the metabolism of other CYP3A4 substrates. In addition, omeprazole lacks an inhibitory effect on the main CYP enzymes.

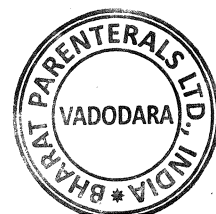
Approximately 3% of the Caucasian population and 15-20% of Asian populations lack a functional CYP2C19 enzyme and are called poor metabolisers. In such individuals the metabolism of omeprazole is probably mainly catalysed by CYP3A4. After repeated once-daily administration of 20 mg omeprazole, the mean AUC was 5 to 10 times higher in poor metabolisers than in subjects having a functional CYP2C19 enzyme (extensive metabolisers). Mean peak plasma concentrations were also higher, by 3 to 5 times. These findings have no implications for the posology of omeprazole.

#### **Excretion:**

The plasma elimination half-life of omeprazole is usually shorter than one hour both after single and repeated oral once-daily dosing. Omeprazole is completely eliminated from plasma between doses with no tendency for accumulation during once-daily administration.

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Almost 80% of an oral dose of omeprazole is excreted as metabolites in the urine, the remainder in the faeces, primarily originating from bile secretion.

The AUC of omeprazole increases with repeated administration. This increase is dose-dependent and results in a non-linear dose-AUC relationship after repeated administration. This time- and dose dependency is due to a decrease of first pass metabolism and systemic clearance probably caused by an inhibition of the CYP2C19 enzyme by omeprazole and/or its metabolites (e.g. the sulphone). No metabolite has been found to have any effect on gastric acid secretion.

#### **Special populations:**

##### **Impaired hepatic function**

The metabolism of omeprazole in patients with liver dysfunction is impaired, resulting in an increased AUC. Omeprazole has not shown any tendency to accumulate with once daily dosing.

##### **Impaired renal function:**

The pharmacokinetics of omeprazole, including systemic bioavailability and elimination rate, are unchanged in patients with reduced renal function.

##### **Elderly:**

The metabolism rate of omeprazole is somewhat reduced in elderly subjects (75-79 years of age).

##### **Paediatric patients:**

During treatment with the recommended doses to children from the age of 1 year, similar plasma concentrations were obtained as compared to adults. In children younger than 6 months, clearance of omeprazole is low due to low capacity to metabolise omeprazole.

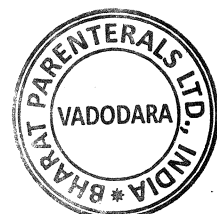
#### **5.3 Preclinical safety data**

Gastric ECL-cell hyperplasia and carcinoids have been observed in life-long studies in rats treated with omeprazole. These changes are the result of sustained hypergastrinaemia secondary to acid inhibition. Similar findings have been made after treatment with H<sub>2</sub>-receptor antagonists, proton pump inhibitors and after partial fundectomy. Thus, these changes are not from a direct effect of any individual active substance.

#### **6. Pharmaceutical particulars:**

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### **MEGASTROLE 20 - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

#### **6.1. List of Excipients:**

The list of excipients is as follows:

Empty Hard Gelatin Capsule Shells Size "2"

#### **6.2 Incompatibilities:**

Not applicable

#### **6.3. Shelf life:**

36 months

#### **6.4. Special precautions for storage:**

Store away from light and in a cool dry place.

#### **6.5. Nature and contents of container:**

Container type: 2 x 7 Alu - Alu blister.

#### **6.6. Special precautions for disposal:**

No special requirement.

#### **7. Applicant**

##### **Name and Address of Applicant**

M/s. Biomedicine Sckivs Pharm.Nig Ltd,

Premise Address: No. 16, Anionwu Street Odoakpu, P.O.BOX:7846, Onitsha Nigeria,

Tel: +234803507884, +2348024517997.

E-mail: sckivspharm@yahoo.com

##### **Name and Address of manufacturer:**

M/s. BHARAT PARENTERALS LIMITED

Survey No. 144 &146, Jarod Samlaya Road,

Village: Haripura, Ta. Savli, Dist. Vadodara – 391520

Gujarat, INDIA.

Tel.91-2667-251680

Fax: 91-2667-251679

E-mail: ra@bplindia.in

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