

## OMEPRAL® Capsules

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

### Information about OMEPRAL

OMEPRAL is available as 20 mg and 40 mg capsule for oral administration containing respectively omeprazole 20 mg and 40 mg processed as microgranules delayed release.

Other ingredients are: sucrose and maize starch, mannitol, sodium lauryl sulfate, polyvidone. Omeprazole is a proton pump inhibitor. It inhibits secretion of gastric acid by irreversibly blocking the (H<sup>+</sup>/K<sup>+</sup> ATPase) enzyme system, the 'proton pump' of the gastric parietal cell, in that it blocks the final step of acid production. It is used in conditions where inhibition of gastric acid secretion may be beneficial, including:

- Treatment of patients with *Helicobacter pylori* infection and peptic ulcer disease in combination with clarithromycin and amoxicillin to eradicate *H. pylori*
- Treatment of active duodenal ulcer
- Treatment of active benign gastric ulcer
- Maintenance of healed peptic ulcers
- Healing of Non-steroidal anti-inflammatory drug NSAID-associated ulcer
- Risk reduction of NSAID-associated ulcer
- Treatment of heartburn and other symptoms associated with gastroesophageal reflux disease GERD
- Treatment of erosive esophagitis
- Maintenance of healing of erosive esophagitis
- Acid-related dyspepsia
- Pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome, multiple adenomas and systemic mastocytosis)
- Prophylaxis of acid aspiration

### The way to take OMEPRAL

Take OMEPRAL as directed by your physician. Do not discontinue the treatment or change the dosage prescribed without consulting your doctor. Take OMEPRAL capsules before eating.

For patients who have difficulty swallowing capsules and in pediatric patients, the capsule may be opened and the contents can be added to applesauce, fruit juice or yogurt and swallowed immediately.

The usual recommended doses for adults are:

Indication	Dose	Duration
<i>H. pylori</i> eradication	<i>Triple therapy:</i> OMEPRAL 20 mg twice daily combined with clarithromycin 500 mg twice daily and amoxicillin 1000 mg (or metronidazole or tinidazole 500 mg) twice daily <i>Dual therapy:</i> OMEPRAL 40 mg once daily combined with clarithromycin 500 mg 3 times daily	Triple therapy regimen is given for 10 days Dual therapy regimen is given for 14 days  OMEPRAL alone may be continued for a further 4 to 8 weeks
Active duodenal ulcer	20 mg once daily	Most patients heal within 4 weeks. Some patients may require an additional 4

		weeks therapy
Active gastric ulcer	40 mg once daily	4 to 8 weeks
Maintenance of healed peptic ulcers	20 mg once daily	
Treatment of NSAID associated ulceration	20 mg once daily	4 to 8 weeks
Prophylaxis in patients with increased risk of gastroduodenal lesions who require NSAID treatment	20 mg once daily	
Symptomatic GERD without esophageal lesions	20 mg once daily	4 weeks
Erosive esophagitis and accompanying symptoms due to GERD	20 mg once daily	4 to 8 weeks
Refractory esophagitis	40 mg once daily	
Maintenance of healing of erosive esophagitis	20 mg once daily	
Relief of acid-related dyspepsia	20 mg once daily	2 to 4 weeks
Pathological hypersecretory conditions	The initial recommended dosage is 60 mg once daily, adjusted as required. Doses up to 120 mg three times daily have been used. Daily doses above 80 mg should be given as divided doses (usually 2).	Continued for as long as clinically indicated
Prophylaxis of acid aspiration during general anesthesia	40 mg the evening before surgery and a further 40 mg two to six hours before the procedure	

No dosage adjustment is required for patients with renal impairment or for the elderly.

*Pediatric use:*

The safety and effectiveness of omeprazole have been established in pediatric patients for the treatment of acid-related gastrointestinal diseases including the treatment of symptomatic GERD, treatment of erosive esophagitis and maintenance of healing of erosive esophagitis.

The usual recommended doses for the symptomatic treatment of GERD and other acid-related disorders:

- Children weighing 5 to 10 kg: 5 mg/day
- Children weighing 10 to 20 kg: 10 mg/day
- Children weighing over 20 kg: 20 mg/day

These doses may be doubled if necessary. The usual recommended dose for children 1 month to 2 years of age is 0.7 mg/kg/day increased if necessary up to 3 mg/kg/day or 20 mg daily.

**In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

**In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

**Contraindications**

This drug is contraindicated in case of known hypersensitivity to any of the components

**Precautions**

- Proton pump inhibitors should be used with caution in patients with hepatic impairment. Consider dose reduction, particularly for maintenance of healing of erosive esophagitis
- Inform your doctor before using this medication in case of pregnancy or lactation. There are no adequate and well-controlled studies on the use of omeprazole during pregnancy. This drug should be used during pregnancy only if clearly needed.
- It is recommended to avoid using this medication during lactation.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently. Use with caution with diazepam, phenytoin, warfarin, digoxin, cyclosporin, disulfiram, benzodiazepine, saquinavir, cilostazol, tacrolimus, voriconazole. Proton pump inhibitors can reduce the absorption of drugs such as ketoconazole, and iron salts whose absorption is dependent on an acid gastric pH. Concomitant use with atazanavir and nelfinavir is not recommended. Co-administration of omeprazole and clarithromycin has resulted in increases in plasma levels of both drugs.

**Adverse reactions**

This drug is usually well tolerated. The most reported adverse reactions include headache, diarrhea, and abdominal pain. Other effects include skin rash, pruritus, dizziness, fatigue, constipation, nausea and vomiting, flatulence, and urticaria.

Occasional reversible confusional states, agitation, depression, and hallucinations have occurred in severely ill patients. Raised liver enzymes, and isolated cases of hepatitis have been rarely reported. Other adverse effects reported rarely or in isolated cases include hyponatremia, blood disorders, and interstitial nephritis.

This drug is usually well tolerated in pediatric patients. The most frequently reported adverse effects in pediatric patients were respiratory effects and otitis media.

Please inform your doctor if any side effect appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

OMEPRAL, Omeprazole 20 mg, pack of 14 capsules

OMEPRAL, Omeprazole 40 mg, pack of 14 capsules

**Revision date: 07/2010**

OMEC2/004