OMEPRAL®
POWDER FOR ORAL SUSPENSION

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
Each sachet of OMEPRAL powder for oral suspension contains 20 mg Omeprazole with the following excipients: magnesium stearate, sodium lauryl sulfate, aspartame, sucrose, raspberry flavor.
Omeprazole is a proton pump inhibitor (PPI). It inhibits secretion of gastric acid by irreversibly blocking the (H^+/K^+ ATPase) enzyme system, the 'proton pump' of the gastric parietal cell, in that it blocks the final step of acid production.
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.
OMEPRAL is used in conditions where inhibition of gastric acid secretion may be beneficial, including:
- Treatment of heartburn and other symptoms associated with gastroesophageal reflux disease GERD
- Treatment of erosive esophagitis
- Maintenance of healing of erosive esophagitis
- Treatment of active duodenal ulcer
- Treatment of active benign gastric ulcer
- Treatment of patients with *Helicobacter pylori* infection in combination with clarithromycin and amoxicillin to eradicate *H. pylori*
- Pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome, multiple adenomas and systemic mastocystosis)
This medicine may be used to treat other conditions as well.

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. OMEPRAL should be taken on an empty stomach at least one hour before a meal.
OMEPRAL powder for oral suspension is suitable for pediatric patients and for adult patients who have difficulty swallowing capsules.
The usual recommended doses for children are as follows:

Indication	**Dosage regimen and duration**		
	Patient age	**Weight-based dose (mg)**	**Regimen and duration**
Treatment of symptomatic GERD	1 to 16 years	5 to less than 10 kg: 5 mg	Once daily for up to 4 weeks
		10 to less than 20 kg: 10 mg	
		20 kg and greater: 20 mg	
Treatment of erosive esophagitis due to acid-mediated GERD	1 to 16 years	5 to less than 10 kg: 5 mg	Once daily for 4 to 8 weeks
		10 to less than 20 kg: 10 mg	
		20 kg and greater:	

		20 mg	
Maintenance of healing of erosive esophagitis due to acid-mediated GERD	1 to 16 years	5 to less than 10 kg: 5 mg	Once daily
		10 to less than 20 kg: 10 mg	
		20 kg and greater: 20 mg	

The usual adult dose range is 20 to 40 mg per day.
No dosage adjustment is required for patients with renal impairment or for the elderly.

Instructions for use:

- Empty packet contents into a small cup containing 15 mL of water.
- Do not use other liquids or foods.
- Stir well and drink immediately.

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

-Dosage reduction is needed in hepatic insufficiency, particularly for maintenance of healing of erosive esophagitis.
-Discontinue the treatment if acute interstitial nephritis develops.
-Use caution in patients with Bartter's syndrome, hypokalemia, hypocalcemia, and problems with acid-base balance.
-PPI therapy may be associated with an increased risk of Clostridium difficile-associated diarrhea, especially in hospitalized patients
-Daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin.
-Hypomagnesemia has been reported rarely in patients treated with PPIs for at least three months.
-Cutaneous lupus erythematosus and systemic lupus erythematosus have been reported in patients taking PPIs.
-PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine.
-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 the potential benefit justifies the potential risk to the fetus; 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.
Omeprazole can reduce the absorption of ketoconazole, atazanavir, nelfinavir, iron salts, erlotinib, and mycophenolate mofetil and increase the absorption of digoxin.
Use caution with diazepam, warfarin, phenytoin, theophylline, propranolol, cyclosporine, disulfiram, benzodiazepines, saquinavir, tacrolimus, and methotrexate.
Avoid the use of rifampin and clopidogrel with this drug.

Adverse reactions

The most frequently reported adverse effects in pediatric patients were respiratory effects, otitis media, fever and accidental injuries.

The most reported adverse reactions in adults include headache, diarrhea, abdominal pain, nausea, vomiting, dizziness, rash, constipation, cough, asthenia, and back pain.
Please inform your doctor if any adverse reaction 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 powder for oral suspension, Omeprazole 20 mg, pack of 12 sachets

Issue date: 11/2016

OMPA2/001