

OMEPRAZOLE

(Capsules)

Composition

Each capsule contains Omeprazole 20 mg.

Inactive Ingredients: Lactose, Microcrystalline Cellulose.

Properties

Omeprazole is a proton pump inhibitor of the gastric parietal cell and thus prevents secretion of gastric acid.

This mechanism of action produces a reversible blockage in the acid secretion at once with a daily dose.

Indications

- Duodenal ulcer disease.
- Zollinger-Ellison syndrome.
- Gastric ulcer.
- Gastro-oesophagic reflux.
- Maintenance treatment.

Contraindications

OMEPRAZOLE is contraindicated for patients with known hypersensitivity to Omeprazole or any other ingredients listed.

Precautions

Pregnancy and Lactation: Omeprazole should not be used in pregnant or nursing women.

Drug Interactions

Omeprazole inhibits the metabolism of drug metabolised by the hepatic cytochrome P450 enzyme system and may increase plasma concentrations of diazepam, phenytoin and warfarin. **It should be concomitantly administered with antibiotics.** There is no interaction with theophylline.

Side Effects

Omeprazole is generally well-tolerated. Adverse effects like nausea, headache, diarrhea, constipation and flatulence are **remotely** related. Some patients reported rash. These adverse effects were mild, temporary and no related with the treatment.

Dosage and Administration

- **Duodenal ulcer disease:** The recommended oral dose is 20 mg (1 capsule) once daily. Most of patients with duodenal ulcer disease reported a fast healing and pain relief in a short term treatment. Patients that reported no improvement needed an additional treatment of two weeks.

Omeprazole has also been reported to be effective in patients with reflux disease refractory to other treatments. A daily dose of 40 mg of omeprazole produced healing within 4 weeks of treatment.

Treatment for longer periods is not yet recommended.

- **Zollinger-Ellison syndrome:** The recommended oral dose is 60 mg (3 capsules) once daily. This dose should be adjusted individually. Doses in the range of 20 to 120 mg daily may be used in more than 90% of patients with severe disease or inadequate response to other treatments. Doses above 80 mg daily should be divided and administered every 12 hours.
- **Gastric ulcer:** The recommended oral dose is 20 mg (1 capsule) once daily. This dose is effective and produces healing at 4 weeks of treatment. Patients that reported no improvement needed an additional treatment of 4 weeks. A dose of 40 mg of omeprazole once daily is recommended in patients with refractory gastric ulcer disease, who reported healing within 8 weeks of treatment. Treatment for longer periods is not recommended.
- **Gastro-oesophagic reflux:** The recommended oral dose is 20 mg (1 capsule) once daily. This dose produces a fast healing in most patients within 4 weeks of treatment. Patients that reported no improvement, needed an additional treatment of 4 weeks. A dose of 40 mg of omeprazole once daily is recommended in patients with refractory gastric ulcer disease, who reported healing at 8 weeks of treatment. Treatment for longer period is not recommended.
- **Maintenance treatment:** OMEPRAZOLE 20 mg once daily is recommended in patients with severe gastro-oesophagic reflux disease in order to avoid relapse. In this case, the dose can be increased to 40 mg/day.
- **Children:** There is no experience with omeprazole in children, so the treatment is not recommended.
- **Old people:** It is not needed a dosage adjustment in aged patients.
- **Patients with impaired renal and/or hepatic function:** It is not necessary to adjust the dosage in patients with altered renal or hepatic function.

Forms and Presentation

OMEPRAZOLE is available in packages of 30 capsules.

Storage

Store in a cool and dry place, below 30°C. Avoid direct sunlight.

Shelf Life

3 years.

THIS IS A MEDICINE

- Medicines are products which affect your health, and failure to follow the instructions may be dangerous for you.
- Follow your doctor's advice carefully, the method of use, and the instructions of the pharmacist who sold you the medicine.
- Your doctor and pharmacist are expert in the use of medicines, and their benefits and risks.
- Do not stop your course of treatment early unless advised to do so by your doctor or pharmacist.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICINES OUT OF THE REACH OF CHILDREN

