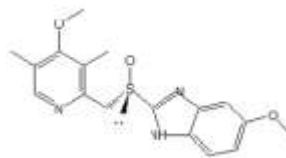


ESOMEPRAZOLE

(Omeprazole is in a class of drugs called proton pump inhibitors (PPI))



GENERIC NAME: omeprazole, omeprazole/sodium bicarbonate

DRUG CLASS AND MECHANISM

Omeprazole is in a class of drugs called proton pump inhibitors (PPI) that block the production of acid by the stomach. Other drugs in the class include lansoprazole (Prevacid), rabeprazole (Aciphex), pantoprazole (Protonix), and esomeprazole (Nexium). Proton pump inhibitors are used for the treatment of conditions such as ulcers, gastroesophageal reflux disease (GERD) and the Zollinger-Ellison syndrome, which are all caused by stomach acid. Omeprazole, like other proton-pump inhibitors, blocks the enzyme in the wall of the stomach that produces acid. By blocking the enzyme, the production of acid is decreased, and this allows the stomach and esophagus to heal. Zegerid contains omeprazole and an antacid (sodium bicarbonate). The FDA approved omeprazole in September 1989.

GENERIC AVAILABLE: Yes (Prilosec)

PRESCRIPTION: Yes; No (Prilosec OTC, Zegerid OTC)

PREPARATIONS: Capsules: 10, 20 and 40 mg. Tablets: 20 mg (Prilosec OTC). Powder for oral suspension: 20 and 40 mg

PRESCRIBED FOR

Omeprazole is used for treating acid-induced inflammation and ulcers of the stomach and duodenum; gastroesophageal reflux disease (GERD); erosive esophagitis, heartburn; prevention of upper gastrointestinal bleeding in critically ill patients; and Zollinger-Ellison Syndrome. It also is used in combination with antibiotics for eradicating *H. pylori* infection of the stomach.

DOSING

For ulcers, GERD, erosive esophagitis and eradication of *H. pylori* the recommended dose for adults is 20-40 mg daily. Ulcer healing usually occurs within 4-8 weeks.

H. pylori infections are treated for 10-28 days.

The usual dose for prevention of upper gastrointestinal bleeding in critically ill patients is 40 mg daily for 14 days.

Prilosec OTC is used for treating heartburn for up to two weeks, and the usual dose is 20 mg daily.

For the management of Zollinger-Ellison Syndrome the starting dose for adults is 60 mg daily, and the dose is adjusted based on either the response of symptoms or the actual measurement of acid production. Doses greater than 80 mg should be divided. Doses up to 120 mg three times a day have been used in the treatment of Zollinger-Ellison Syndrome.

For maximal efficacy, omeprazole tablets should be taken before meals, swallowed whole and should not be crushed, chewed or opened.

DRUG INTERACTIONS

Omeprazole potentially can increase the concentrations in blood of diazepam (Valium), warfarin (Coumadin), and phenytoin (Dilantin) by decreasing the elimination of these drugs by the liver.

The absorption of certain drugs may be affected by stomach acidity. Therefore, omeprazole as well as other PPIs reduce the absorption and concentration in blood of ketoconazole (Nizoral) and increase the absorption and concentration in blood of digoxin (Lanoxin). This may reduce the effectiveness of ketoconazole or increase digoxin toxicity.

Through unknown mechanisms, omeprazole may increase blood levels of saquinavir and reduce blood levels of nelfinavir and atazanavir, drugs that are used for treating patients with infection caused by the human immunodeficiency virus (HIV). Accordingly, the dose of saquinavir may need to be reduced to avoid toxicity, and the doses of nelfinavir and atazanavir may need to be increased to maintain efficacy.

USES

Omeprazole works by blocking acid production in the stomach. This medication is known as a proton pump inhibitor (PPI). It is used to treat acid-related stomach and throat (esophagus) problems (e.g., acid reflux or GERD, ulcers, erosive esophagitis, or Zollinger-Ellison syndrome). In addition, it may be used in combination with antibiotics to treat certain types of intestinal ulcers caused by bacterial infection. In the US, this medication is nonprescription and is used to treat frequent heartburn (occurring 2 or more days a week). It is important if you are taking this medication for self-treatment to read the manufacturer's package instructions carefully so you know when to consult your doctor or pharmacist.

HOW TO USE

Take this medication by mouth usually once daily, 15-30 minutes before a meal, or as directed by your doctor. Do not crush, break or chew the

medication. Swallow the medication whole. Take with a full glass of water (8 oz. or 240 ml). Antacids may be taken along with this medication, if needed. The dosage and length of treatment is based on your medical condition and response to therapy. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. Continue to take this medication for the prescribed length of treatment even if you are feeling better. The US nonprescription product is not intended to provide immediate relief of heartburn. It may take up to 1-4 days before the full benefit of this drug is seen. The self-treatment course for heartburn is usually 14 days. If your heartburn persists after this period of time or worsens, or if you require more than one treatment course every 4 months, then contact your doctor or pharmacist. Inform your doctor if your condition persists or worsens.

SIDE EFFECTS

Constipation, cough, dizziness or back pain may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: signs of vitamin B-12 deficiency with long-term (over 3 years) treatment (e.g., unusual weakness, sore tongue, numbness or tingling of the hands/feet). A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking omeprazole, tell your doctor or pharmacist if you are allergic to it; or to similar drugs (e.g., lansoprazole, esomeprazole); or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heartburn for more than 3 months, heartburn combined with lightheadedness/sweating/dizziness, chest pain or shoulder/jaw pain especially with trouble breathing, frequent chest pain, pain spreading to arms/neck/shoulders, unexplained weight loss, trouble or pain swallowing food, liver problems, persistent nausea/vomiting/stomach pain, blood in vomit or stools (vomit that looks like coffee grounds, black stools), other stomach problems (e.g., tumors). This drug may make you dizzy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: confusion, unusual sweating, blurred vision, unusually fast heartbeat.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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