Omeprazole

Hovizol

Proton Pump Inhibitor

Description

Pellet filled light caramel opaque and flesh opaque capsule.

Formulation

Each capsule contains Omeprazole 20 mg.

Action and Pharmacology

Omeprazole is activated at an acidic pH to a sulphenamide derivative that binds irreversibly to H^+/K^+ ATPase, an enzyme system found at the secretory surface of parietal cells. It thereby inhibits the final transport of hydrogen ions (via exchange with potassium ions) into the gastric lumen. Since the H^+/K^+ ATPase enzyme system is regarded as the acid (proton) pump of the gastric mucosa, omeprazole is known as a gastric acid pump inhibitor. Omeprazole inhibits both basal and stimulated acid secretion irrespective of the stimulus.

Omeprazole is rapidly absorbed, but not to a variable extent, following oral administration. Absorption of omeprazole is not affected by food. The absorption of omeprazole, as well as being formulation-dependent, also appears to be dose-dependent, as increasing dosage above 40 mg has been reported to increase the plasma concentrations in a non-linear fashion. Following absorption, omeprazole is almost completely metabolised in the liver, primarily by cytochrome P450 isoform CYP2C19. It is eliminated 72 to 80% through renal and 18 to 23% through fecal. In dialysis, it is not readily dialyzable because of extensive protein binding.

Indications

Omeprazole is indicated for:

- treatment of reflux oesophagitis.
- duodenal ulcer; benign gastric ulcer.
- long term treatment of pathologic gastric hypersecretion associated with Zollinger-Ellison syndrome.

Side Effects/Adverse Reactions

- Cases of haematologic abnormalities, specifically anemia (unusual tiredness or weakness), eosinopenia, leukocytosis (sore throat and fever), neutropenia (continuing ulcers or sore in mouth), pancytopenia or thrombocytopenia (unusual bleeding or bruising), haematuria (bloody urine), proteinuria (cloudy urine), urinary tract infection (difficult, burning, or painful urination, frequent urge to urinate or bloody or cloudy urine).
- Abdominal pain and colic.
- Asthenia (unusual tiredness, muscle pain); central nervous system (CNS) disturbances, specifically dizziness, headache, somnolence (unusual drowsiness), or unusual tiredness; chest pain; gastrointestinal disturbances, specifically acid regurgitation (heartburn), constipation, diarrhoea or loose stools, flatulence (gas), or nausea and vomiting; skin rash or itching.

Precautions/Warnings

- Before giving omeprazole to patients with gastric ulcers the possibility of malignancy should be considered since omeprazole may mask symptoms and delay diagnosis.
- Omeprazole is extensively metabolised in the liver and some sources recommended that dosage should be reduced in hepatic impairment.
- Risk-benefit should be considered when the following medical problems exist: chronic, current or history of hepatic disease where dosage reduction may be required due to increased half-life.

Use in pregnancy and lactation

- Adequate and well-controlled studies in humans have not been done. There is no evidence on the safety of omeprazole in human pregnancy. Animal studies have revealed no teratogenic effect, but reproduction studies have revealed reduced litter weights. Avoid in pregnancy unless there is no safer alternative.
- It is not known whether omeprazole is excreted in human milk. However, because omeprazole has been shown to cause tumorigenic and carcinogenic effects in animals, a decision should be made on whether nursing should be discontinued or the medication withdrawn, taking into account the importance of the omeprazole to the mother.

Contraindications

- Contraindicated in patients known to be hypersensitive to omeprazole

Drug Interactions

- Since omeprazole may increase gastrointestinal pH, concurrent use with ampicillin esters, iron salts or ketoconazole may result in a reduction in absorption of these medications.
- Inhibition of the cytochrome P-450 enzyme system by omeprazole, especially in high doses, may cause a decrease in the hepatic metabolism of anticoagulants (coumarin or indandione-derivative) or diazepam or phenytoin, which may result in delayed elimination and increased blood concentrations, when these medications are used concurrently with omeprazole.
- Concurrent use of omeprazole with bone marrow depressants may increase the leukopenic and/or thrombocytopenic effects of both these medications; if concurrent use is required, close observation for toxic effects should be considered.

Symptoms and treatment for Overdosage

Clinical features

No information available on the effects of overdosage in man.

Treatment for overdosage

Since there is no specific antidote, treatment should be symptomatic and supportive.

Dosage and Administration

Omezole capsules are recommended to be taken immediately before meals, preferably in the morning and swallowed whole with liquid. For patients with swallowing difficulties the capsule might be opened and the contents swallowed or suspended in a slightly acidic fluid e.g juice, soured milk, or non-carbonated water. The dispersion should be taken immediately or within 30 minutes. Alternatively patients can suck the capsule and swallow the pellets with liquid. The pellets must not be chewed or crushed.

Usual adult and adolescent dose:

- ***Reflux Oesophagitis***: The recommended dosage is Omezole 20 mg once daily. Symptom resolution is rapid and in most patients healing occurs within 4 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 4 weeks treatment period. In patients with severe reflux oesophagitis, Omezole 40 mg once daily is recommended and healing is usually achieved within 8 weeks.
- ***Duodenal Ulcer/ Benign Gastric Ulcer***: Oral, 20 mg once a day. The dosage can be increased to 40 mg once a day for duodenal/gastric ulcer refractory to other treatment regimens. If healing of gastric ulcer has not occurred within 4 weeks, an additional 4 weeks of treatment is recommended. Long term therapy for patients with history of recurrent duodenal ulcer is recommended at a dosage of 20 mg Omezole once daily, up to one year.
- ***Gastric hypersecretory (e.g., Zollinger-Ellison)***: Oral, 60 mg once a day, the dosage being adjusted as needed, and therapy continued for as long as clinically indicated.
- Dose adjustment is not required in the elderly.
- ***Impaired renal function***: Dose adjustment is not required in patients with impaired renal function.
- ***Impaired hepatic function***: As bioavailability and plasma half-life of omeprazole are increased in patients with impaired hepatic function, a daily dose of 20 mg may be sufficient.

Caution : Food, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Note : The information given here is limited. For further information, consult your doctor or pharmacist.

Storage : Store at temperature below 25°C. Protect from moisture.

Presentation/Packing : Capsule 20 mg x Blisters of 4 x 7's.

Registration No. : DRP-1219

Date of Renewal of Authorization : January 4, 2018

Manufactured by : HOVID Bhd., 121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia

Imported & Distributed by : HOVID Inc., Unit B, 7th Floor, Karina Building, 33 Shaw Boulevard, Pasig City, Philippines.

Information Date : November 2018