Opzol 20mg Capsules 40mg Injection

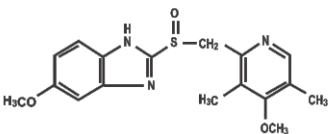
(Omeprazole)

اوپضول

(اومیپرازول)

DESCRIPTION

Opzol (Omeprazole), a substituted benzimidazole, is a proton pump inhibitor that inhibits gastric acid secretion. Chemically omeprazole is 5-methoxy-2-[[(4-methoxy-3, 5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1Hbenzimidazole. The molecular formula is $C_{17}H_{19}N_3O_3S$ and the structural formula is:



Omeprazole

QUALITATIVE & QUANTITATIVE COMPOSITION

Opzol (Omeprazole) is available for oral administration as:

1. Opzol Capsule 20mg
   Each capsule contains:
   Omeprazole enteric coated pelletseq. to omeprazole 20mg
2. Opzol injection 40mg
   Each vial contains
   Omeprazole sodium eq. to omeprazole 40mg

CLINICAL PHARMACOLOGY

Mechanism of Action

Omeprazole reduces gastric acid secretion through a unique mechanism of action. Omeprazole belongs to a new class of anti-secretory compounds, the substituted benzimidazoles that do not exhibit anti-cholinergic or histamine antagonistic properties. It inhibits secretion of gastric acid by irreversibly blocking the enzyme system of hydrogen/potassium adenosine triphosphatase (H^+/K^+ ATPase), the proton pump of the gastric parietal cell. This effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus.

Pharmacokinetics

Absorption/Distribution

Omeprazole is acid-labile and is administered orally as enteric-coated pellets in capsules. Omeprazole is rapidly but variably absorbed following oral administration, with peak plasma levels of omeprazole occurring within 0.5 to 3.5 hours. Absorption of omeprazole is not affected by food and also appears to be dose dependant. Increasing the dosage above 40mg has been reported to increase plasma concentrations in a non-linear fashion because of saturable first pass metabolism. Absorption is higher after long-term administration.

The systemic bioavailability of omeprazole is approximately 35%. After repeated once daily administration, the bioavailability increases to about 60%.The plasma protein binding is approximately 95%.

Metabolism & Excretion

Following absorption, omeprazole is almost completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 to form hydroxy-omeprazole and to a small extent by CYP3A to form omeprazole sulfone. These metabolities are inactive and excreted mostly in the urine and to a lesser extent in the bile. The majority of the dose (about 77%) is eliminated in the urine and the remainder, recoverable in the feces. The elimination half-life from plasma is reported to be about 0.5 to 3 hours.

Special Populations

Pediatric

Available data from children (1 year and older) suggest that the pharmacokinetics within the recommended doses are similar to those reported in adults. At steady state, lower plasma levels of omeprazole were seen in some children.

Geriatric

The bioavailability of omeprazole is not significantly altered in patients with reduced renal function. Therefore dose adjustment is not required.

Renal Insufficiency

The systemic bioavailablity of omeprazole is not significantly altered in patients with reduced renal function. Therefore dose adjustment is not required.

Hepatic Insufficiency

The area under the plasma concentration-time curve is increased in patients with impaired liver function, but no tendency to accumulation of omeprazole has been found.

THERAPEUTIC INDICATIONS

Opzol (Omeprazole) is indicated for the treatment of:

1. Gastro-Esophageal Reflux Disease (GERD):
   - Treatment of erosive reflux esophagitis.
   - Long term management of patients with healed esophagitis to prevent relapse.
   - Symptomatic treatment of gastroesophageal reflux disease (GERD).
2. Gastric and duodenal ulcer.
3. Treatment and prophylaxis of NSAID-associated ulceration.
4. Eradication of *Helicobacter pylori* infection associated with peptic ulcer disease.
5. Zollinger-Ellison Syndrome.
6. Dyspepsia.
7. Prophylaxis of acid aspiration.

DOSAGE & ADMINISTRATION

Opzol (Omeprazole) capsule is given by mouth, which should be swallowed whole and not crushed or chewed.

Symptomatic gastro-esophageal reflux disease (GERD) without esophagitis:

The recommended adult oral dose is 20mg daily for up to 4 weeks.

Erosive esophagitis:

The recommended adult oral dose for the treatment of patients with erosive esophagitis and accompanying symptoms due to GERD is 20mg daily for 4 to 8 weeks.

Maintenance of healing of erosive esophagitis:

The recommended adult oral dose is 20mg daily.

Dosage for children in GERD:

In children, doses in the ranges 0.7 to 1.4mg per kg body weight daily, up to a maximum daily dose of 40mg have been given for 4 to 12 weeks.

Gastric and duodenal ulcer:

A single daily dose of 20mg by mouth or 40mg in severe cases is given. Treatment is continued for 4 weeks for duodenal ulcer and 8 weeks for gastric ulcer. Where appropriate, a dose of 10 to 20mg once daily may be given for maintenance.

NSAID-associated ulceration:

Doses of 20mg daily are used in the treatment of NSAID-associated ulceration. A dose of 20mg daily may also be used for prophylaxis in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment.

Helicobacter pylori eradication:
For the eradication of *H. pylori* in peptic ulceration omeprazole 40mg daily may be combined with antibacterials in dual therapy or omeprazole 20mg twice daily may be combined with antibacterials in triple therapy. Omeprazole alone may be continued for a further 2 to 8 weeks.

Zollinger-Ellison syndrome:
The initial recommended dosage is 60mg by mouth once daily, adjusted as required. The majority of patients are effectively controlled by doses in the range 20 to 120mg daily, but doses up to 120mg three times daily have been used. Daily doses above 80mg should be administered in divided doses.

Dyspepsia:
For the relief of acid-related dyspepsia omeprazole is given in usual doses of 10 or 20mg daily by mouth for 2 to 4 weeks.

Prophylaxis of acid aspiration:
Omeprazole is also used for the prophylaxis of acid aspiration during general anesthesia, in a dose of 40mg the evening before surgery and a further 40mg two to six hours before the procedure.

Dosage for Hepatic Impaired Patients:
A maximum daily dose of 20mg is recommended for patients with impaired hepatic function.

ADVERSE EFFECTS
Omeprazole is well tolerated and the adverse reactions have generally been mild and reversible.

Common
Central and peripheral nervous system: Headache.
Gastrointestinal: Diarrhea, constipation, abdominal pain, nausea/vomiting and flatulence.

Uncommon
Central and peripheral nervous system: Dizziness, paresthesia, somnolence, insomnia and vertigo.
Hepatic: Increased liver enzymes.
Skin: Rash and/or pruritis, urticaria.
Other: Malaise.

Rare
Central and peripheral nervous system: Reversible mental confusion, agitation, aggression, depression and hallucinations, predominantly in severely ill patients.
Endocrine: Gynecomastia.
Gastrointestinal: Dry mouth, stomatitis and gastrointestinal candidiasis.
Hematological: Leukopenia, thrombocytopenia, agranulocytosis and pancytopenia.

Gastro-duodenal carcinoids have been reported in patients with Zollinger-Ellison syndrome on long-term treatment with omeprazole.

CONTRAINDICATIONS
Omeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted benzimidazoles.

PRECAUTIONS
General:
- When gastric ulcer is suspected, the possibility of malignancy should be excluded as treatment may alleviate symptoms and delay diagnosis.
- Prior to initiation of dual or triple therapy, the physician should consider the patient with known hypersensitivity reactions to penicillin, macrolides and other antibiotics.

Hepatic impairment:
Consideration should be given to reducing the dose of omeprazole in patients with impaired hepatic function as bioavailability and half-life can increase.

Pregnancy:
There are no adequate or well-controlled studies in pregnant women. Omeprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:
It is not known whether omeprazole is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from omeprazole, a decision should be made whether, to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Drug Interactions
- In common with the use of other inhibitors of acid secretion or antacids, the absorption of ketoconazole, and itraconazole can decrease during treatment with omeprazole due to decreased intragastric acidity during treatment with omeprazole.

- Omeprazole is metabolized by CYP2C19. Thus, when omeprazole is combined with drugs metabolized by CYP2C19, such as diazepam, citalopram, impiramine, clomipramine, phenytoin etc., the plasma concentrations of these drugs may be increased and a dose reduction could be needed.

STORAGE
Store below 30°C.
Protect from sunlight and moisture.

The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED
Opzol (omeprazole) 20mg capsulers are available in 14's and 10x10's blister packs size.

Opzol (omeprazole) 40mg injection are available in blister packs size of 1's.

Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

Please read the contents carefully before use.
This package insert is continually updated from time to time.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں یا تفصیلی
ہدایات کیلئے ڈبے کے اندر موجود پرچہ ملاحظہ کریں۔
ہدایات: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔

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