Omedar®

دار الدواء
Dar Al Dawa

Omeprazole

DESCRIPTION:
Omedar® is omeprazole which is a proton pump inhibitor.

PHARMACOLOGY:
Omeprazole reduces the gastric acid secretion through a highly selective mechanism of action; it produces specific and dependent inhibition of the enzyme H^+/K^+ ATPase (the proton pump) in the parietal cell. The final stage of gastric acid secretion is inhibited regardless of the stimulus to acid formation.
The absorption of omeprazole starts only after leaving the stomach. The absorption is rapid, with peak plasma level occurring within 0.5 - 3.5 hours. Plasma half - life is 0.5 - 1 hours. Protein binding is approximately 95%. The majority of the dose (about 77%) is eliminated in the urine, the remainder of the dose is excreted in the faeces.

INDICATIONS:
- Duodenal ulcer.
- Gastric ulcer.
- NSAID associated gastric and duodenal ulcers or erosions.
- *Helicobacter pylori* eradication in peptic ulcer disease.
- Reflux oesophagitis.
- Symptomatic gastro-oesophageal reflux disease.
- Acid related dyspepsia.
- Zollinger-Ellison syndrome.

CONTRAINDICATIONS:
Omedar® is contraindicated in patients with known hypersensitivity to omeprazole.

SIDE EFFECTS:
Omedar® is well tolerated and adverse reactions have generally been mild and reversible. The following events have been reported but in many cases a relationship to treatment with omeprazole has not been established:
- Skin: Rarely rash and/or pruritus. In isolated cases photosensitivity, erythema multiforme, alopecia, Stevens-Johnson syndrome, toxic epidermal necrolysis.
- Musculoskeletal: In isolated cases arthralgia, muscular weakness and myalgia.
- Central and peripheral nervous system: Headache. Rarely dizziness, paraesthesia, somnolence, insomnia and vertigo. In isolated cases reversible mental confusion, agitation, aggression, depression and hallucinations, predominantly in severely ill patients.
- Gastrointestinal: Diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence. In isolated cases dry mouth, stomatitis and gastrointestinal candidiasis.
- Hepatic: Rarely increased liver enzymes. In isolated cases encephalophathy in patients with pre-existing severe liver disease; hepatitis with or without jaundice, hepatic failure.
- Endocrine: In isolated cases gynaecomastia.
- Haematological: In isolated cases leukopenia, thrombocytopenia, agranulocytosis and pancytopenia.
- Other: Rarely malaise. Hypersensitivity reactions e.g. urticaria (rarely) and in isolated cases angioedema, fever, bronchospasm, interstitial nephritis and anaphylactic shock. In isolated cases increased sweating, peripheral oedema, blurred vision, taste disturbance and hyponatremia.

WARNINGS AND PRECAUTIONS:
- In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment may alleviate symptoms and delay diagnosis.
- Pregnancy and lactation: No adverse effects of omeprazole have been noted on pregnancy or on the health of the fetus/newborn child. **Omedar®** can be used during pregnancy.
  Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.
- Effects on ability to drive and use machines: Omeprazole is not likely to affect the ability to drive or use machines.

DRUG INTERACTIONS:
- The absorption of ketoconazole and itraconazole can decrease during ompeprazole treatment.
- No interaction with amoxycillin has been found.
- No interaction with food or concomitantly administered antacids has been found.
- As omeprazole is metabolized in the liver through cytochrome P450 2C19 (CYP2C19), it can prolong the elimination of diazepam, warfarin (R-warfarin) and phenytoin. Monitoring of patients receiving warfarin and phenytoin is recommended and a reduction of phenytoin or warfarin dose may be necessary.
- Plasma concentrations of omeprazole and clarithromycin are increased during concomitant administration.

DOSAGE AND ADMINISTRATION:
Omedar® tablets are recommended to be given in the morning and swallowed whole with liquid. The contents of the tablet should not be chewed or crushed.
The tablets may be dispersed in water or a slightly acidic fluid such as fruit juices. The dispersion should be taken within 30 minutes. To ensure that you have taken all of the medication, rinse the glass with half a glass of fluid and drink.
- **Duodenal ulcer:** The recommended dosage in patients with an active duodenal ulcer is 20 mg once daily. Symptom resolution is rapid and in most patients healing occurs within 2 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 2 weeks' treatment period.
  In patients with poorly responsive duodenal ulcer a dosage of 40 mg once daily is recommended and healing is usually achieved within 4 weeks.
  For the prevention of relapse in patients with duodenal ulcer disease the recommended dose is 10 mg once daily. If needed, the dose can be increased to 20-40 mg once daily.
- **Gastric ulcer:** The recommended dosage is 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 poorly responsive gastric ulcer a dosage of 40 mg once daily is recommended and healing is usually achieved within 8 weeks.
  For the prevention of relapse in patients with poorly responsive gastric ulcer the recommended dose is 20 mg once daily. If needed, the dose can be increased to 40 mg once daily.
- **NSAID associated ulcer or gastroduodenal erosions:** The recommended dosage is 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.
  For the prevention of NSAID associated gastric ulcer, duodenal ulcers, gastroduodenal erosions and dyspeptic symptoms the recommended dosage is 20 mg once daily.
- **Helicobactor pylori (Hp) eradication regimens in peptic ulcer disease:** Triple therapy regimens: **Omedar®** 20 mg, amoxicillin 1 g and clarithromycin 500 mg, all twice a day for one week or **Omedar®** 20 mg, metronidazole 400 mg (or tinidazole 500 mg) and clarithromycin 250 mg, all twice a day for one week.
  In each regimen if the patient is still Hp positive, therapy may be repeated.
- **Reflux oesophagitis:** The recommended dosage is 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 a dosage of 40 mg once daily is recommended and healing is usually achieved within 8 weeks.
  For the long-term management of patients with healed reflux oesophagitis the recommended dose is 10 mg once daily. If needed, the dose can be increased to 20-40 mg once daily.
- **Symptomatic gastro-oesophageal reflux disease:** The recommended dosage is 20 mg daily. Symptom relief is rapid. Patients may respond adequately to 10 mg daily, and therefore individual dose adjustment should be considered.
  If symptom control has not been achieved after 4 weeks' treatment with 20 mg daily, further investigation is recommended.
- **Acid related dyspepsia:** In the relief of symptoms in patients with epigastric pain/discomfort with or without heartburn the recommended dosage is 20 mg once daily. Patients may respond adequately to 10 mg daily and therefore this dose could be considered as a starting dose. If symptom control has not been achieved after 4 weeks' treatment with 20 mg daily, further investigation is recommended.
- **Zollinger-Ellison syndrome:** In patients with Zollinger-Ellison syndrome the dosage should be individually adjusted and treatment continued as long as is clinically indicated. The recommended initial dosage is 60 mg daily. All patients with severe disease and inadequate response to other therapies have been effectively controlled and more than 90% of the patients maintained on doses of 20-120 mg daily. When doses exceed 80 mg daily, the dose should be divided and given twice daily.
- **Impaired renal function:** Dose adjustment is not needed 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 10-20 mg may be sufficient.
- **Elderly:** Dose adjustment is not needed in the elderly.

OVERDOSAGE:
Single oral doses of up to 400 mg of omeprazole have not resulted in any severe symptoms. The rate of elimination was unchanged with increased doses and no specific treatment has been needed.

PRESENTATIONS:
Omedar® Enteric-Coated Tablets: Packs of 14 tablets. Each tablet contains 10 mg Omeprazole.
Omedar® Enteric-Coated Tablets: Packs of 14 tablets. Each tablet contains 20 mg Omeprazole.

STORAGE CONDITIONS:
Store below 25°C.

This is a medicament.
- *Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.*
- *Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold you the medicament.*
- *The doctor and the pharmacist are experts in medicine, its benefits and its risks.*
- *Do not, by yourself, interrupt the period of treatment prescribed.*
- *Do not repeat the same prescription without consulting your doctor.*

Keep medicament out of reach of children

Manufactured by Dar Al Dawa, Na'ur - Jordan

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