ZIMOR

Omeprazole

Capsules

COMPOSITION: per capsule
Omeprazole (INN) . . . . . 20 mg
Excipients q.s.

PROPERTIES
Omeprazole acts to inhibit the proton pump in the gastric parietal cells. It thus reduces the secretion of gastric acid by means of a new mode of action. It acts rapidly and brings about reversible control of the secretion of stomach acid with only one daily dose.

INDICATIONS
- Short term treatment of duodenal ulcer
- Zollinger-Ellison syndrome
- Gastric ulcer
- Reflux oesophagitis

DOSAGE
- Duodenal Ulcer: The recommended dose is 20 mg (1 capsule) once daily. In the majority of those patients with duodenal ulcer, relief of symptoms follows rapidly and healing occurs in the first two weeks of treatment. In patients whose ulcers have not been able to heal completely during this initial cycle, healing generally occurs during an additional period of two weeks of treatment.
In patients with duodenal ulcers which are refractory to other treatment regimes, a dose of 40 mg (2 capsules) once daily has been used and healing generally occurred within a period of 4 weeks.
Due to the fact that experience with prolonged treatment is limited, maintenance treatment is not recommended until more data is available.

- Zollinger-Ellison syndrome: The recommended initial dose is 60 mg (3 capsules) once daily. This should be adjusted individually and treatment should be continued as long as it is clinically indicated. More than 90% of patients with severe complaints and with inadequate reponse to other treatments have been effectively brought under control with dosages of 20 to 120 mg daily. If the dosage exceeds 80 mg daily, it should be divided up and administered in two doses per day, one each 12 hours.

- Gastric ulcer: The recommended dose is 20 mg (1 capsule) once daily. Relief of symptoms is rapid, and in the majority of patients, healing occurs in the first four weeks of treatment. In those patients whose ulcers have not been able to heal completely during this initial cycle, this generally occurs during and additional period of four weeks of treatment. In patients with gastric ulcers which are refractory to other treatment regimes, ZIMOR has been utilised at a dose of 40 mg once daily and healing was generally attained within a period of eight weeks. Due to the fact that experience with prolonged treatment of patients with gastric ulcer is limited, maintenance treatment is not recommended until more experience is accumulated.

- Reflux oesophagitis: The recommended dose is 20 mg (1 capsule) once daily. Relief of symptoms is rapid and, in the majority of patients, healing occurs within the first four weeks of treatment.

In those patients whose ulcers have not healed completely during this initial cycle, healing generally occurs during an additional period of four weeks of treatment.

In patients with reflux oesophagitis which is refractory to other treatment regimes, ZIMOR has been utilised at a dose of 40 mg once daily and healing is generally attained within a period of eight weeks.

Due to the fact that experience with prolonged treatment of patients with reflux oesophagitis is limited, maintenance treatment is not recommended until more experience is accumulated.

- Children: There is no experience in paediatrics so that it is not recommended in children.

- Elderly patients: It is not necessary to carry out any adjustments to the previously shown dosage for elderly patients.

- Disturbed renal and/or hepatic function: It is not necessary to adjust the dosage in patients with deterioration of the renal function. It is recommended to reduce the maximum daily dose to 20 mg in patients with impaired hepatic function.

CONTRAINDICATIONS
Zimor capsules are contraindicated in patients with known hypersensitivity to any component of the formulation.

PRECAUTIONS
In pregnancy and breast-feeding before treatment the presence of gastric malignancy should be excluded. Use during pregnancy and lactation: as with all new medicines, omeprazole should not be administered during pregnancy and lactation unless its use is considered indispensable.

Carcinogenesis: In two 24-month carcinogenicity studies in rats, omeprazole (at doses approximately 4 to 352 times the human dose) produced gastric ECL cell carcinoids in a dose-related manner the incidence of this effect was higher in female rats. Gastric carcinoids seldom occur in the untreated rat. A 78-week mouse carcinogenicity study of omeprazole did not show increased tumor occurrence, but the study was not conclusive.

Mutagenesis: Omeprazole was not mutagenic in an in vitro Ames Salmonella typhimurium assay, an in vitro mouse lymphoma cell assay and an in vivo rat liver DNA damage assay. A mouse micronucleus test at 625 and 6250 times the human dose gave a borderline result, as did an in vivo bone marrow chromosome aberration test. A second mouse micronucleus study at 2000 time the human dose, was negative.

Impairment of fertility: In a rat fertility and general reproductive performance test, omeprazole was not toxic or deleterious to the reproductive performance of parental animals.
Teratology: Teratology studies conducted in pregnant rats and in pregnant rabbits did not disclose any evidence for a teratogenic potential of omeprazole.
In rabbits, omeprazole (in doses approximately 17 to 172 times the human dose) produced dose-related increases in embryo-lethality, fetal resorptions and pregnancy disruptions. In rats, dose-related embryo/fetal toxicity and postnatal developmental toxicity were observed (at doses approximately 35 to 345 times the human dose). There are no adequate or well-controlled studies in pregnant women.

Nursing mothers: It is not known whether omeprazole is excreted in human milk. In rats, omeprazole administration during late gestation and lactation (at doses 35 to 345 times the human dose) resulted in decreased weight gain in pups. Because many drugs are excreted in human milk, 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.

INTERACTIONS
Omeprazole can delay the elimination of diazepam and phenytoin as these are medicines which are metabolised in the liver by cytochrome P450. It is recommended that patients being treated simultaneously with phenytoin be monitored since it may be necessary to reduce the dose of anticonvulsant.
No reactions have been encountered with theophylline. Nonetheless, there may be interactions with other medicines that are also metabolised by this oxidation system such as warfarin. No interactions have appeared with simultaneously administered antacids.

ADVERSE REACTIONS
Omeprazole is well tolerated. In rare cases, nausea, headache, diarrhoea, constipation and flatulence have been reported. In some patients a rash has appeared. In general, these symptoms were slight and transient and did not have any subsequent connection with the treatment.

INTOXICATION AND TREATMENT
Rare reports have been received of overdosage with omeprazole. Doses ranged from 320 mg to 900 mg (16-45 times the usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache, and dry mouth. Symptoms were transient, and no serious clinical outcome has been reported. No specific antidote for omeprazole overdosage is known. Omeprazole is extensively protein bound and is, therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

PRESENTATION
Package with 14 capsules of 20 mg.
Package with 28 capsules of 20 mg.

ONLY AVAILABLE WITH PHYSICIAN'S PRESCRIPTION

Medicines should be kept out of the reach of children

Store below 25°C

Protect from light and moisture

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