SOLCER SR

Omeprazole Delayed Release Capsules USP 20 mg

COMPOSITION :
Each Hard Gelatin Capsule Contains :
Omeprazole USP 20mg
(As Enteric Coated Pellets)
Excipients ..... q.s.
Approved Colours used in Empty Capsule Shells

PHARMACOLOGICAL CLASSIFICATION : Proton pump inhibitor.

MECHANISM OF ACTION :
Omeprazole is a gastric proton pump inhibitor, i.e. omeprazole directly and dose-dependently inhibits the enzyme H^+, K^+- ATPase, which is responsible for the gastric acid secretion in the gastric parietal cells. Due to this selective intracellular mode of action that is independent of other membrane-bound receptors (such as the histamine H_2, muscarine M, or gastrinergic receptors), omeprazole has been assigned to a separate class of acid-inhibiting agents, which block the final step of acid production.

As a consequence of its mode of action, omeprazole leads to an inhibition of both basal and stimulable acid secretion, irrespective of the stimulus type.

Thus, omeprazole increases the pH-value and reduces the volume of gastric acid secretion. As a weak base the prodrug omeprazole accumulates in the acid environment of the parietal cells and will only become effective as an inhibitor of the H^+,K^+- ATPase after being protonised and rearranged.

In an acid environment at a pH of less than 4, the protonised omeprazole is converted to omeprazole sulphenamide, the active substance.

Compared to the plasma half-life of the omeprazole base, omeprazole sulphenamide remains in the cell for a longer period of time. A sufficiently low pH-value is only found in the gastric parietal cells; this explains the high specificity of omeprazole. It is the omeprazole sulphenamide that binds to the enzyme and inhibits its activity.
If the enzyme-system is inhibited, the pH-value increases and less omeprazole accumulates or is converted in the gastric parietal cells.

Consequently, the accumulation of omeprazole is regulated by a kind of feedback-mechanism.
In long-term treatment, omeprazole, as a result of acid inhibition, causes a moderate gastrin increase. Mild to moderate increase in ECL-cells occurs during long-term use. Carcinoids as found in animal experiments were not seen in humans yet.

Most available clinical experience from controlled randomised clinical trials indicate that 20 mg omeprazole twice daily in combination with two antibiotics for 1 week achieve >80% H. pylori eradication rate in patients with gastro-duodenal ulcers. As expected, significantly lower eradication rates were observed in patients with baseline metronidazole-resistent H. pylori isolates. Hence, local information on the prevalence of resistance and local therapeutic guidelines should be taken into account in the choice of an appropriate combination regimen for H. pylori eradication therapy. Furthermore, in patients with persistent infection, potential development of secondary resistance (in patients with primary susceptible strains) to an antibacterial agent should be taken into account in the considerations for a new retreatment regimen. Clinical evidence additionally indicates that, following successful eradication therapy in patients with peptic ulcer disease, relapse rates of dudenaal ulcers and most likely also gastric ulcers are exceptionally low in comparison to the natural course of the disease with ongoing infection.

INDICATIONS :
Solcer SR capsules are indicated for :
- Duodenal ulcers
- Benign gastric ulcers
- Reflux oeaophagitis
- Maintenance treatment of reflux oesophagitis to prevent relapse
- Zollinger-Ellison syndrome
- Treatment and prophylaxis of NSAID related gastric and duodenal ulcers
- Maintenance treatment of NSAID related gastric and duodenal ulcers to prevent relapse
- Symptomatic treatment of gastrooesophageal reflux disease

DOSAGE AND ADMINISTRATION :
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.

CONTRA-INDICATIONS :
Omeprazole is contraindicated in patients with known hypersensitivity to omeprazole or any other component of the formulation. Omeprazole should not be administered with atazanavir due to an important reduction in atazanavir exposure.

WARNING AND PRECAUTIONS :
In patients with peptic ulcer disease Helicobacter pylori-status should be determined if relevant. In patients who are shown to be Helicobacter pylori-positive, the elimination of the bacterium by eradication therapy should be aimed at wherever possible.

If a gastric ulcer is suspected, the possibility of malignancy must be excluded before treatment with Omeprazole is instituted, as treatment may alleviate symptoms and delay diagnosis. The diagnosis of reflux oesophagitis should be confirmed endoscopically.

Decreased gastric acidity, due to any means - including proton-pump inhibitors - increases gastric counts of bacteria normally present in the gastro-intestinal tract. Treatment with acid-reducing drugs leads to a slightly increased risk of gastrointestinal infections, such as Salmonella and Campylobacter.

Omeprazole should be used with caution in elderly and in hepatic and renal dysfunction. especially in high doses. In severe hepatic dysfunction the daily dose should be 20 mg at maximum.

In patients with severe impaired hepatic function, liver enzyme values should be checked periodically during treatment with Omeprazole. Before the treatment of NSAID-related ulcers, the possibility of stopping the intake of the causative agent should strongly be considered.

The maintenance treatment of ulcers associated with the intake of non-steroidal anti-inflammatory drugs should be restricted to patients at risk.

In long-term use especially when exceeding 1 year, a regular review of the treatment and a periodic and thorough benefit-risk assessment should be performed by the physician.

During therapy with omeprazole requiring a combined administration of drugs (NSAID related ulcers or eradication) caution should be exercised when administering additional drugs as interactions might add up or potentiate.

During combination treatment caution should also be exercised in patients with renal or hepatic dysfunction.

Omeprazole should not be used in infants and children under the age of 2.

In severely ill patients the monitoring of visual and auditory senses is recommended as isolated cases of blindness and deafness have been reported in the use of the injection form of omeprazole.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabcorption should not take this medicine.
PREGNANCY AND LACTATION :
Limited epidemiologic studies indicate no adverse effects on pregnancy or increases in general malformation rate.

However, there is insufficient information with respect to specific abnormalities.

In rats, omeprazole and its metabolites are excreted into milk. There is insufficient data on exposure of babies via
breast milk. Omeprazole concentration in human breast milk reaches ca. 6% of the maximum plasma concentration in the mother.

Use of omeprazole during pregnancy and lactation requires a careful benefit-risk-assessment.

UNDESIRABLE EFFECTS :

Gastrointestinal disorders

Common (10%-1%): diarrhoea, constipation, flatulence (possibly with abdominal pain), nausea and vomiting. In the majority of these cases the symptoms improve if the therapy is continued.

Rare (0.1%-0.01%): brownish-black discoloration of the tongue during concomitant administration of clarithromycin and benign glandular cysts; both were reversible after cessation of treatment.

Very rare (<0.01%): dryness of the mouth, stomatitis, candidiasis or pancreatitis.

Hepato-biliary disorders

Uncommon (1%-0.1%): changes in liver enzyme values (which resolve after discontinuation of therapy).-

Very rare (<0.01%): hepatitis with or without jaundice, hepatic failure and encephalopathy in patients with pre-existing severe liver disease. Blood and the lymphatic system disorders

Rare (0.1%-0.01%): hypochrome, microcytic anemia in children.

Very rare (<0.01%): changes in blood count, reversible thrombocytopenia, leucopenia or pancytopenia and agranulocytosis.

Skin and subcutaneous tissue disorders :

Uncommon (1%-0.1%): pruritus, skin eruptions, alopecia, erythema multiforme or photosensitivity and increased tendency to sweat

Very rare (<0.01%): Stevens-Johnson-syndrome or toxic epidermal necrolysis.

Musculoskeletal disorders

Rare (0.1%-0.01%): muscle weakness, myalgia and joint pain.

Renal disorders

Very rare (<0.01%): nephritis (interstitial nephritis)

Nervous system disorders

Common (10%-1%): drowsiness, somnolence, sleep disturbances (insomnia), vertigo and headaches. These complaints usually improve during continued therapy.

Rare (0.1%-0.01%): paresthesia, light-headedness. Mental confusion and hallucinations in predominantly severely ill or elderly patients.

Very rare (<0.01%): agitation and depressive reactions in predominantly severely ill or elderly patients.

Disorders in sensory organs

Uncommon (1%-0.1%): visual disturbances (blurred vision, loss of visual acuity or reduced field of vision) and auditory dysfunction (e. g. tinnitus) or taste disturbances.

These conditions usually resolve on cessation of therapy.

Hypersensitivity reactions

Very rare (<0.01%): urticaria, elevated body temperature, angioedema, bronchoconstriction or anaphylactic shock, allergic vasculitis and fever have been reported.

Other adverse effects

Uncommon (1%-0.1%): peripheral oedema (which resolved on cessation of therapy)

Very rare (<0.01%): hyponatremia, gynaecomastia.

DRUG INTERACTIONS :
Omeprazole can delay the elimination of diazepam, phenytoin and warfarin. Reduction of warfarin or phenytoin dose may be necessary when Omeprazole is added to the treatment. There is no evidence of interaction with theophylline, propranolol or antacids.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT :
The symptoms described in connection to omeprazole overdosage have been transient, and no serious outcome due to omeprazole has been reported. The rate of elemination was unchanged (first order kinetics) with increased doses and no specific treatment has been needed.

STORAGE: Store below 30^0C & protect from light. Keep Medicines out of reach of children

PRESENTATION: 4 x 7 tablets in a carton.

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