OMEPRAZOLE CAPSULES

Omicap-20

COMPOSITION:
Each capsule contains: Omeprazole BP 20 mg (As enteric coated granules).

CHEMISTRY:
Chemically, it is described as 5-methoxy-2-[{(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl}sulfinyl]-1H-benzimidazole.

PHARMACOLOGICAL CATEGORY:
'Proton Pump' Inhibitors.

PHARMACOLOGY:
Pharmacodynamics: Omeprazole markedly inhibits basal and stimulated gastric acid secretion. It has a unique mode of irreversibly blocking the so called proton pump of the parietal cells which is supposedly the terminal step in the acid secretory pathway.

Pharmacokinetics: Omeprazole is rapidly absorbed after release from enteric coated formulations. Peak plasma concentration of Omeprazole occurs within 0.5 to 3.5 hours following oral administration. Enteric coating increases bioavailability to over 65%. Plasma protein binding of it is about 95-96%. Omeprazole is eliminated rapidly and almost completely by metabolism. Three metabolites observed in plasma are sulfide and sulfone derivatives of Omeprazole and hydroxyomeprazole . These metabolites have very little or no antisecretory activity.

INDICATIONS AND USES:
Duodenal and gastric ulcers, Zollinger Ellison syndrome, Reflux oesophagitis.

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

SIDE EFFECTS / ADVERSE REACTIONS:
The most frequent side effects reported with Omeprazole are Clostridium difficile-associated diarrhoea (CDAD); fractures, headache, diarrhoea, abdominal colic, nausea, dizziness, vomiting, rash, flatulence, constipation, cough & asthenia. They are mainly transient and do not require a reduction in dose.

PRECAUTIONS AND WARNINGS:
Omeprazole produces a dose related increase in gastric carcinoid tumours. Biopsy specimen from human stomach have not detected risk from short term exposure to Omeprazole. Further human data on the effect of sustained hypochlorhydria and hypergastrinemia are needed to rule out the possibility of an increased risk for the development of tumors in human receiving long term therapy with Omicap (Omeprazole).

Use in children:
Omeprazole is not recommended for use in children.

Clostridium difficile-associated diarrhoea
Published observational studies suggest that proton pump inhibitor (PPI) therapy like Omeprazole, may be associated with an increased risk of Clostridium difficile- associated diarrhoea (CDAD), especially in hospitalised patients. This diagnosis should be considered for diarrhoea that does not improve (see Adverse Reactions). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.

Bone Fracture
Several published observational studies suggest that proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established treatment guidelines (see Dosage and Administration and Adverse Reactions).

Concomitant use of Omeprazole with Methotrexate
Literature suggests that concomitant use of PPIs with methotrexate (primarily at high dose; see methotrexate prescribing information) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. In high-dose methotrexate administration a temporary withdrawal of the PPI may be considered in some patients (see Drug Interactions).

DRUG INTERACTIONS:
Omeprazole has the potential to interfere with the Cytochrome P450 enzyme system and then to induce or inhibit the metabolism of drugs like diazepam, warfarin and phenytoin. Because of its profound and long lasting inhibition of gastric acid secretion,
Omeprazole may interfere with absorption of drugs where gastric pH is an important determination of their bioavailability (eg. Ketoconazole, Ampicillin, Esters and Iron salts).

Methotrexate
Case reports, published population pharmacokinetic studies, and retrospective analyses suggest that concomitant administration of PPIs and methotrexate (primarily at high dose; see methotrexate prescribing information) may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate. However, no formal drug interaction studies of methotrexate with PPIs have been conducted (see Warnings and Precautions).

USE IN PREGNANCY AND LACTATION:
Pregnancy: The safety of Omicap (Omeprazole) in human pregnancy has not been established. Omeprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactation: Breast feeding should be discontinued by women being treated with Omeprazole.

DOSAGE AND ADMINISTRATION:

Active gastric duodenal ulcers	- 20 mg/day for 2 to 4 weeks.
Severe duodenal ulcer	- 40 mg/day for 4 to 8 weeks.
Reflux oesophagitis	- 20 mg/day for 4 to 8 weeks.
Severe erosive oesophagitis	- 20 to 40 mg/day for 4 to 8 weeks.
Zollinger - Ellison syndrome	- 60 mg/day duration adjusted to response.

Dosage adjustment is not necessary in elderly patients or in patients with renal or hepatic impairment.

OVERDOSAGE:
There is no experience to date with deliberate over dosage. Dosage up to 360mg/day are well tolerated. No specific antidote is known. Omeprazole is extensively protein bound and is therefore not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

STORAGE:
Store below 25°C, in a dark and dry place.

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