OMCAP
(Omeprazole) 20 mg

اوم کیپ
(اومیپرازول)

OMCAP capsules 20 mg: Hard gelatin capsules with transparent blue body and cap, printed "Platinum" on both.
Each capsule contains
Omeprazole (U.S.P)..... 20 mg
(Enteric-coated granules)
Product Complies U.S.P. Specs.

Description
OMCAP (omeprazole) reduces gastric acid secretion through a highly selective mechanism of action. It produces specific dose dependent inhibition of the enzyme H+, K –ATPase (the 'proton pump') in the parietal cell. As this action inhibits the final stage of gastric acid formation, there is effective inhibition of both basal and stimulated acid secretion irrespective of the stimulus to acid formation. Omeprazole has no effect on acetylcholine or histamine receptors and no clinically significant pharmacodynamic effects have been observed other than those explained by the effect of omeprazole on acid secretion. The onset of action is rapid and reversible. Control of gastric acid secretion is achieved with once daily dosing.

Uses / Indications
OMCAP is indicated for
Treatment of duodenal ulcer
Treatment of gastric ulcer
Treatment of reflux oesophagitis
Management of Zollinger-Ellison Syndrome

Contraindications
There are no known contraindications to the use of OMCAP.

Precautions
When gastric ulcer is suspected, the possibility of malignancy should be excluded as treatment may alleviate symptoms and delay diagnosis.

Use In pregnancy and lactation
As with all new drugs, OMCAP should not be given during pregnancy and lactation unless its use is considered essential. Animal studies have not shown evidence of any hazard from the administration of OMCAP during pregnancy and lactation and there is no evidence of foetal toxicity or teratogenic effect.

Adverse reactions
OMCAP is well tolerated. Nausea, headache, diarrhoea, constipation and flatulence have been reported but are rare and skin rash has occurred in a few patients. These events have been transient and usually mild and there has been no consistent relationship with treatment.

Dosage and administration
Duodenal ulcer, gastric ulcer and reflux oesophagitis
The recommended dosage is 20 mg OMCAP once daily.
In patients with duodenal ulcer symptom relief is rapid and healing occurs within 2 weeks in most cases. For those patients who may not have fully healed after the initial course, healing usually occurs during a further 2 week treatment period.

In patients with gastric ulcer or reflux oesophagitis symptom relief is rapid and healing occurs within 4 weeks in most cases.
For those patients who may not have fully healed after the initial course, healing usually occurs during a further 4 weeks treatment period.

In patients refractory to other treatment regimens, 40 mg OMCAP once daily has been used and healing achieved. Usually within 4 weeks in patients with duodenal ulcer and within 8 weeks in patients with gastric ulcer or reflux oesophagitis.

Zollinger-Ellison syndrome
The recommended initial dosage is 60 mg OMCAP once daily. The dosage should be adjusted individually and treatment continued as long as is clinically indicated. 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. With doses above 80 mg daily, the dose should be divided and given twice daily.

Impaired renal and liver function
Dose adjustment in patients with impaired renal or liver function is not required.

Children
There is no experience with OMCAP in children.

Elderly
No dose adjustment is necessary in the elderly.

Interactions
OMCAP can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolised by oxidation in the liver. Monitoring of patients also receiving warfarin or phenytoin is recommended and a reduction of dose of phenytoin and warfarin may be necessary. No interaction with propranolol or theophylline has been found. But interactions with other drugs also metabolised via the cytochrome P450 enzyme system cannot be excluded. No interaction with concomitantly administered antacids has been found.

Incompatibilities
None known yet.

Overdosage
There is no information available on the effects of overdosage in man and specific recommendations for treatment cannot be given.

Single oral doses of up to 160 mg have been well tolerated.

Presentation:
OMCAP 20 mg available in Alu Alu blister pack of 2x7 capsules.

Store below 30°C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

Manufactured by:
Platinum
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