SANAMIDOL

20 mg Omeprazole
ORAL
HOW SUPPLIED
Packages of 14 capsules.
COMPOSITION
Each capsule contains:
Omeprazole ..... 20 mg
Excipient: q.s.
ACTIONS
SANAMIDOL produces inhibition of the proton pump in the gastric parietal cell. Thus, it reduces gastric acid secretion through a new mechanism of action. The onset of action is rapid and reversible control of gastric acid secretion is achieved with only a daily dosing.
INDICATIONS
- Duodenal ulcer.
- Gastric ulcer.
- Reflux esophagitis
- Zollinger-Ellison Syndrome.
- Prevention of recurrence in severe reflux esophagitis.

DOSAGE
Duodenal ulcer: The recommended oral dosage is 20 mg (1 capsule) once daily. 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 refractory to other treatment regimens, 40 mg (2 capsules) once daily has been used and healing achieved, usually within 4 weeks.
Gastric ulcer: The recommended oral dosage is 20 mg (1 capsule) once daily. Ulcer 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 week treatment period. In patients refractory to other treatment regimens, 40 mg (2 capsules) once daily has been used and healing achieved, usually within 8 weeks.
Reflux esophagitis: The recommended oral dosage is 20 mg (1 capsule) once daily. Ulcer 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 week treatment period. In patients with severe reflux esophagitis, 40 mg (2 capsules) once daily has been used and healing achieved, usually within 8 weeks.
Prevention of recurrence in severe reflux esophagitis. Maintenance therapy: The recommended dosage is 20 mg (1 capsule) once daily to avoid recurrence in patients with severe reflux esophagitis. In the event of recurrence the dose can be increased to 40 mg (2 capsules) once daily.
Zollinger-Ellison Syndrome: The recommended initial dosage is 60 mg (3 capsules) 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 in children. Therefore, its use in children is not recommended.
Elderly patients: No dosage adjustment is necessary for the elderly.
CONTRAINDICATIONS
There are no known contraindications to the use of SANAMIDOL.
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 drugs, SANAMIDOL 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 Omeprazole during pregnancy and lactation and there is no evidence of foetal toxicity or teratogenic effect.
INTERACTIONS
SANAMIDOL can prolong the elimination of diazepam and phentonytoin, 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. However, concomitant treatment with SANAMIDOL daily did not change the blood concentration of phenytoin in patients on continuous treatment with phenytoin. No interaction with propranol, metoprolol, theophylline, lidocaine, quinidine and amoxycillin has been found, but interactions with other drugs also metabolised via the cytochrome P450 enzyme system cannot be excluded. No interaction with concomitantly administered antiacids has been found.
SIDE EFFECTS
SANAMIDOL is well tolerated. The following events have been reported, but in most cases a consistent relationship between these events and treatment with omeprazole has not been established.
Dermatologic: Rarely, rash, urticaria and/or pruritus.
Musculosketal: In isolated cases, arthralgia, muscular weakness and myalgia.
Peripheral and central nervous system: Headache. Rarely, dizziness, paresthesia, drowsiness, insomnia and vertigo. In isolated cases, reversible mental confusion, agitation, depression and hallucination, predominantly in severaly ill patients.
Gastrointestinal: Diarrhea, constipation, abdominal pain, nausea/vomiting and flatulence. In isolated cases, stomatitis, and gastrointestinal candidiasis.
Hepatic: In isolated cases, increased liver enzymes with or without increased bilirubin values.
Endocrine: In isolated cases, gynecomastia.
Hematologic: In isolated cases, leukopenia, and thrombocytopenia.
Others: Rarely, malaise. In isolated cases, peripheral edema, blurred vision and taste perversion.
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 and dosages of up to 360 mg/day have been well tolerated.
Single i.v. doses of up to 80 mg have been well tolerated. Dosages of up to 200 mg/day and of up to 520 mg during a period of 3 days have been administered i.v. and no adverse effects have been reported.
UNDER MEDICAL PRESCRIPTION ONLY
DRUGS SHOULD BE KEPT OUT OF CHILDREN'S REACH

Pharminicio, S.L.
Paseo de la Habana
28036 Madrid
SPAIN

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