ULCESEP

OMEPRAZOLE

COMPOSITION

Each capsule contains:
Omeprazole (D.C.I.) ..... 20 mg.
Inactive ingredients: Saccharose Phtalate hydroxypropyl methylcellulose,CornStarch, Hydroxypropyl methyl cellulose, Lactose, Hydroxypropyl cellulose, Crystallised disodium phosphate, Lauryl sodium sulphate, Diethyl Phtalate. Covering: Hard gelatine, colorants (C.I. 73015, C.I. 47005, C.I. 77891).

HOW SUPPLIED

Capsules of hard gelatin containing micropellets of omeprazole with enteric coating. Packages of 28 capsules in aluminum blisters.

PROPERTIES

ULCESEP® acts by inhibition the acid (proton) pump in the gastric parietal cell reducing the secretion of gastric acid. Acts rapidly and produces a reversible control of the acid secretion of the stomach.

HOLDER AND MANUFACTURER

LABORATORIOS CENTRUM, S.A. (A.S.A.C. Pharma)
Sagitario, 14 - 03006 ALICANTE (Spain)

INDICATIONS

- Duodenal ulcer and benign gastric ulcer (including those provoked by NSAIs)
-Treatment and prevention of Gastroesophageal reflux disease, severe symptoms of no inflammatory disease due to reflux and light symptoms which not responding to traditional treatment.
-Zollinger-Ellison Syndrome
- Gastric and duodenal ulcer; treatment of ulcer with Helicobacter pylori infection (eradication of Helicobacter pylori).
- Long term maintenance treatment of gastroduodenal ulcer and peptic esophagitis

CONTRA INDICATIONS

Known hypersensivity to Omeprazole.

PRECAUTIONS

ULCESEP® has been prescribed just for your current disease. Do not take this drug for other diseases without your physician's previous consent.

INTERACTIONS

Before starting treatment with ULCESEP® inform your physician if you are taking any other medication. The concomitant administration of ULCESEP® with other medicaments can produce interactions: diazepam in anxiety prevention, warfarin in blood coagulation or phenytoin in epilepsy; because of that it can be necessary that your physician reduces dose.

During treatment with ULCESEP® you can take antacids

Treatment with ULCESEP® will not be affected with a concomitant administration of anti-inflammatory of meal.

WARNINGS

Pregnant and lactating women: In pregnant women or nursing mothers should take a special care with drugs. ULCESEP® should not be administered unless its use is indispensable. You should advise to your physician in case you make pregnant during treatment with ULCESEP®

Pediatric use: pediatric experience with ULCESEP® is reduced

Elderly use: dosage adjustment is not necessary

Renal or hepatic impairment: In patients with severe hepatic impairment is seldom necessary dosage above 10-20 mg per day. No dosage adjustment is necessary for patients with impairment of renal function.

Effect on driving ability and machinery use. ULCESEP® is safe and it is unlikely an effect on your ability to drive or to use machinery.

DOSAGE

Form and way of administration. The recommended administration of ULCESEP® is in the morning. Your physician will indicate number of capsules and when you have to take them. Capsules should be taken fasting or together with the meal. Capsules should not be opened, chewed or crushed and should be swallowed as a whole.

Dosage, frequency and duration of treatment:

Duodenal ulcer, gastric ulcer, gastroesophageal reflux: depending on the severity of ulcer or inflammation, the recommended dose is 20-40 mg (1 or 2 capsules) daily for 28 weeks.

For maintenance treatment of duodenal ulcer and gastroesophageal reflux, the recommended dose is 20 mg (1 capsule) daily for 6 to 12 months.

Gastroesophageal reflux symptomatic disease: the recommended dose is 20 mg (1 capsule) daily.

Gastric and duodenal ulcers or erosions due to treatment with anti-inflammatories: the recommended dose is 20 mg (1 capsule) daily for 4 to 8 weeks.

Eradication of Helicobacter pylori in peptic ulcers. The recommended dose is 40 mg (2 capsules) twice a day, or 20 mg (1 capsule) of ULCESEP® twice a day, concomitantly administered with following antibiotics:

Triple Therapy:

20 mg (1 capsule) of ULCESEP® + 1 g of Amoxicillin + 500 mg of Clarithromycin twice a day for 1 week or

20 mg (1 capsule) of ULCESEP® + 250 mg of Clarithromycin + 400 mg of Metronidazole (or 500 mg of Tinidazole) twice a day for 1 week or

40 mg (2 capsules) of ULCESEP® once a day + 500 mg of Amoxicillin + 400 mg of Metronidazole both three times a day for a week

Dual Therapy:

40-80 mg (2-4 capsules) of ULCESEP® daily + 1.5 g of Amoxicillin daily in divided dosages for two weeks or.

40 mg (2 capsules) of ULCESEP® daily + 500 mg of Clarithromycin three times a day for 2 weeks.

In order to assure healing in patients suffering from active peptic ulcers, see recommended dose for gastric and duodenal ulcer. If after all possible treatments patient remains being Helicobacter pylori positive, treatment can be repeated.

Zollinger Ellison Syndrome: the initial recommended dose is 60 mg. (3 capsules) of ULCESEP® daily. This dose should be individually adjusted and the treatment should continue following your physician's indication. If the dosage is above 80 mg (4 capsules) of ULCESEP® daily, must be divided and administered in two daily doses. one every 12 hours.

In case forgetfulness of taking a dose: Take your dose immediately and after continue your regimen. Nevertheless, if there are just few hours left up to your following dose, wait until following capsule.

OVERDOSAGE

Although no symptoms have been observad in patients who have taken an extremely high dose of Omeprazole, inform your physician or pharmacist in case of overdose.

Oral single doses up to 400 mg (20 capsules) have not been provoked severe effects.

For further information, consult your local Toxicological Information Service.

SIDE EFFECTS

ULCESEP® is well tolerated. Rare cases have been reported of nausea, headache, diarrhea, constipation and flatulence. In some patients it has been reported skin eruptions. These symptoms were generally light and disappeared after discontinuation of treatment. If any adverse reaction not previously described is observed, consult with your physician or pharmacist.

STORAGE CONDITIONS

Keep stored at room temperature, in its original package

EXPIRATION DATE

This product must not be used beyond the expiration date specified on the package

WITH DOCTOR' S PRESCRIPTION

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Laboratorio CENTRUM,S.A.
De A.S.A.C. Pharma
C/ Sagitario, 14 - ALICANTE (Spain)