

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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GASTRISEC® 20 mg CAPSULES

- The active ingredient is omeprazole.
Each capsule contains 20 mg of omeprazole.
- The excipients are as follow: sugar spheres, anhydrous lactose, hypromellose, sodium laurilsulfate, hydroxypropyl-cellulose, disodium phosphate dihydrate, hypromellose phthalate and diethyl phthalate.
- The gelatin capsule is composed of gelatin, indigotine (E-132) and quinoline yellow (E-104).

Marketing Authorisation Holder:

KORHISPANA, S.L.
Carretera de Castellvell, 24
43204 REUS (Tarragona) Spain

Manufacturer:

INDUSTRIA QUÍMICA Y FARMACÉUTICA VIR, S.A.
Laguna 66-68-70, 28923 ALCORCON (MADRID) SPAIN

1. What GASTRISEC® 20 mg CAPSULES are and what they are used for

They are presented as hard gelatin capsules containing gastro-resistant granules. Specifically, they are in boxes containing 14 or 28 capsules. The active ingredient is omeprazole. This medicine works by reducing the amount of acid produced in your stomach. Omeprazole capsules may be used for:

- Treatment of duodenal and benign gastric ulcers including complicating NSAID therapy.
- Treatment and prophylaxis of NSAID-associated duodenal ulcers, duodenal ulcers and gastroduodenal erosions in risk patients (elderly and/or patients with a previous history of gastroduodenal lesions) who require continued NSAID treatment.
- Treatment of gastro-oesophagitis reflux disease.
- Treatment of Zollinger-Ellison syndrome, where the stomach produces large amounts of acid.
- Treatment of duodenal and gastric ulcers related to bacteria called *Helicobacter Pylori* (this bacteria has influence in the appearance of ulcer).

2. Before you take GASTRISEC® 20 mg CAPSULES

Do not take GASTRISEC® 20 mg CAPSULES:

- If you are allergic to omeprazole or any of the other ingredients of GASTRISEC® 20 mg CAPSULES.

Taking GASTRISEC® 20 mg CAPSULES with food and drink:

The contents of the capsule must not be dissolved in water for its administration. If you have difficulty to swallow the whole capsule you can open the capsule and dissolve the contents in a slightly acid liquid such as juice, yoghurt or sour milk, although, if it is possible, it is preferable to swallow the whole capsule.

Pregnancy:

Ask your doctor or pharmacist for advice before taking any medicine.

Like any medication, omeprazole must not be administered during pregnancy unless your doctor considers it indispensable. Therefore, you should let your doctor know as soon as possible in case of getting pregnant during the treatment.

Breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine. Like any medication, omeprazole must not be administered during the breast-feeding period unless your doctor considers it indispensable.

Driving and using machines:

Your medicine does not usually affect your ability to drive or operate machinery.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The administration of omeprazole may decrease the absorption of Ketoconazole, a medicine used for the treatment of fungal infections. Omeprazole can interfere with the elimination of some medicines, such as warfarin (a medicine used to avoid the coagulation of blood) and phenytoin (a medicine for epilepsy treatment). When omeprazole is administered together with clarithromycin (antibiotic) the concentrations of both medicines increase in blood.

Omeprazole can decrease the absorption of Vitamin B12(cobalamin), which has to be taken into account in patients with deficiency in cobalamin.

There could be interaction with omeprazole and cyclosporine.

When omeprazole is administered together with triazolam, diazepam or flurazepam (medicines used for anxiety and insomnia) the risk of appearance of movement alterations that these medicines cause can be increased. If it is associated to disulfiram (a medicine to treat alcoholism), muscle rigidity may appear.

3. How to take GASTRISEC® 20 mg CAPSULES

GASTRISEC® 20 mg CAPSULES are administered orally.

- In the treatment of duodenal ulcer, gastric ulcer, in the treatment of esophagitis by reflux, it is recommended to administer one or two capsules (20 to 40 mg) a day, depending on the seriousness.
- In the maintenance treatment of the duodenal ulcer and reflux oesophagitis the dosage recommended is of a capsule (20 mg) a day.
- In the treatment of the symptoms of gastro-oesophageal reflux disease it is recommended a capsule (20 mg) a day.
- In the treatment of ulcers or gastric and duodenal erosions associated to a maintenance treatment with non-steroidal anti-inflammatory drugs it is recommended a capsule (20 mg) a day.
- In the treatment of eradication of *Helicobacter Pylori* in the peptic ulcer:
- Administration of omeprazole plus two antibiotics: it is recommended to administer 2 capsules (40 mg) a day or a capsule (20 mg) twice a day, plus two antibiotics, according to the doctor decision.
- Administration of omeprazole plus an antibiotic: from two to four capsules (40 to 80 mg) of omeprazole a day plus an antibiotic.



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- Zollinger-Ellison syndrome: the initial recommended dosage is of 3 capsules (60 mg) a day. The dosage will have to be adjusted individually. Higher dosages than 4 capsules (80 mg) a day must be shared in two intakes.

GASTRISEC® 20 mg CAPSULES are administered preferably in the morning, swallowing the whole capsules with a little liquid. Patients with difficulty to swallow can either open the capsules and take the contents or dissolve them in a slightly acid liquid such as juice, yoghurt or sour milk. In case of mixing them with a liquid it must be taken in less than 30 minutes. The contents of the capsules can also be swallowed directly, but the granules must never be chewed or ground.

Follow these directions unless your doctor has given you other different directions.

Remember to take your medicine.

Your doctor will indicate the duration of GASTRISEC® 20 mg CAPSULES. Do not stop the treatment earlier even though the symptoms improve quickly, since the nuisances might reappear.

- In the treatment of duodenal ulcer, of the gastric ulcer, and in the treatment of reflux oesophagitis, it is recommended a treatment from 2 to 8 weeks.
- In the maintenance treatment of the duodenal ulcer and reflux oesophagitis it is recommended a treatment of 6 to 12 weeks.
- In the treatment of ulcers or gastric and duodenal erosions associated to a maintenance treatment with non steroidal anti-inflammatory drugs it is recommended a treatment from 4 to 8 weeks.
- In the treatment of eradication of *Helicobacter Pylori* in the peptic ulcer the duration of the treatment depends on the antibiotics used together with omeprazole, being possible to extend it for one to two weeks, being sometimes necessary the treatment repetition.
- In the treatment of Zollinger-Ellison syndrome the doctor will establish the treatment duration.

If you take more GASTRISEC® 20 mg CAPSULES than you should

Check with your doctor or pharmacist. In case of overdose or accidental consumption, check with the Toxicological Information Service indicating the product and the quantity consumed.

If you forget to take GASTRISEC® 20 mg CAPSULES do not take a double dosage to make up for the forgotten dosage. Take the forgotten dosage as soon as it is possible and then follow the usual timetable. However, if it is nearly time for your next dose just take the next dose and forget about the one you missed.

4. Possible side effects

Like all medicines, GASTRISEC® 20 mg CAPSULES can cause side effects. These are usually mild and go away when you stop taking this medicine. The following side effects have been produced, although it has not been possible to establish a relationship with omeprazole treatment.

Dermatological: Eruption and/or itchiness rarely appear. Sometimes sun allergy and hair loss may appear.

Muscles and skeleton: In some isolated cases the following have been produced, pain in the articulations, numbness, itchiness, weakness and muscle pain.

Nervous system: Headache. Rarely dizziness, hot flushes, drowsiness, insomnia and vertigo. In isolated cases, mental reversible confusion, disorientation, restlessness, depression and hallucinations, especially in patients severely ill and decrease of consciousness in patients with pre-existent hepatic disease.

Gastrointestinal: Diarrhoea, constipation, abdominal pain, nausea or vomit and flatulence. In isolated cases, mouth dryness, gum inflammation and intestinal infection by fungi.

Hepatic: Rarely alterations in laboratory tests. In isolated cases encephalopathies (brain alteration produced by liver disease) in patients with previous hepatic disease, hepatitis or hepatic insufficiency.

Endocrine: In isolated cases, increase of breast size.

Blood: In isolated cases decrease of certain cells that can be found in blood (leukopenia, thrombocytopenia, granulocytosis and pancytopenia).

Other: Rarely, general discomfort. Allergic reactions and in isolated cases angioedema (liquid retention), fever, bronchial spasms, kidney diseases and allergic shock. In isolated cases increase of sweating, liquid retention, blurred vision and taste alteration. In long treatments there can be a slight increase in the frequency of cysts of stomach. This is produced due to the inhibition of the acid secretion that omeprazole produces, but it is benign and reversible.

If you notice any side effects not listed, please tell your doctor or pharmacist.

5. How to store GASTRISEC® 20 mg CAPSULES

Special conditions of preservation are not required.

Keep GASTRISEC® 20 mg CAPSULES out of the reach of children.

Expiry date

Do not use GASTRISEC® 20 mg CAPSULES after the expiry date stated on the box.

This leaflet has been approved in June 2003

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