PACKAGE LEAFLET: INFORMATION FOR THE USER

GASTRISEC 40 mg

Powder for solution for infusion

Omeprazole

Read all of this leaflet carefully before you start using 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 for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

In this leaflet:

1. WHAT GASTRISEC IS AND WHAT IT IS USED FOR

Gastrisec is used to treat certain diseases in which there is excessive gastric acid production.
Gastrisec is used to treat the following diseases:

- **Duodenal ulcer**: erosion or breakdown of duodenal lining
  Gastric ulcer: erosion or breakdown of stomach lining
- **Reflux oesophagitis**:a condition in which ingested foods or liquids leak back from the stomach to the oesophagus
  Zollinger-Ellison Syndrome: a condition in which there is increased production of the hormone gastrin, leading to excessive production of acid.

This medicine is solely for hospital use.

2. BEFORE USING GASTRISEC 40 mg

Do not use this medicine:
- If you are allergic (hypersensitive) to Gastrisec or any of the other ingredients of Omeprazole.

Take special care with GASTRISEC
If you experience any symptoms which alarm you (e.g. unexplained and significant weight loss, repeated vomiting, difficulty swallowing, vomiting blood, bloody stools), and if you have actual or suspected erosion or breakdown of stomach lining, Gastrisec may hide the symptoms and delay diagnosis of other diseases, so your doctor must be sure that there is no malignant process before prescribing omeprazole.

Always consult your doctor if you have ever experienced any of the symptoms described above.

This medicine contains less than 23 mg sodium per dose,i.e. is essentially “sodium-free”.

Using other medicines:
Tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

If you use omeprazole, it is very important to tell your doctor if you are using:
- Azolic anti-fungal agents (such as itraconazole or ketoconazole)used to treat infections caused by a fungus.
- Diazepam (e.g. Valium) used to treat anxiety.
- Oral anti-coagulants (such as warfarin) used to thin the blood.
- Anti-epileptic drugs (such as carbamazepine or phenytoin) used to treat several types of convulsions and seizures.
- Macrolides (antibiotics such as clarithromycin and erythromycin) used to treat certain infections caused by bacteria.

Pregnancy and breast-feeding
Consult your doctor or pharmacist before using any kind of medicine.

Driving and using machines:
Not likely to affect your ability to drive or use any tools or machines.

3. HOW TO USE GASTRISEC 40 mg

Always use Gastrisec exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure.
The usual dose is one daily dose of Omeprazole administered intravenously. (The dose is adjusted according to individual patient needs and may be higher).

Before treatment begins, it must be established that you are not suffering from any malignant oesophagus or stomach condition, as omeprazole may hide the symptoms and delay diagnosis.

For patients with Zollinger-Ellison Syndrome, the recommended starting dose is 60 mg daily (administered intravenously). The dose is adjusted according to individual patient needs and may be higher.When the dose is higher than 60 mg daily, it must be administered in two daily doses.

Impaired liver function: Liver disorders may affect the omeprazole dose you require. In patients with impaired liver function, a daily dose of 10-20 mg is usually sufficient given the increased amount of Gastrisec in the organism.

Children: Experience is limited, therefore Gastrisec is not recommended for children.

The elderly: There is no need to adjust the dosages described above for elderly patients.

If you use more GASTRISEC than you should:
This medicine is unlikely to cause overdose. If you have inadvertently taken more Gastrisec than you should have, drink plenty of water and inform your doctor or pharmacist immediately, or contact the Toxicology Information Service on telephone number 0034 91 562 04 20 giving the name of the medicine and the amount ingested.

If you forget to use GASTRISEC:
Do not take a double dose to make up for the forgotten dose.
If you have any other questions about taking this medicine, ask your pharmacist or doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Gastrisec can cause side effects, although not everybody gets them.

Gastrisec is well tolerated and side effects are usually slight and reversible. During the clinical trials carried out and the post-marketing follow-up, the side effects described below have been recorded, although in the majority of cases no causal relationship has been established between these side effects and omeprazole treatment. To classify the side effects, the definitions described below have been used:
Common: affects more than 1 user in 100
Uncommon: affects more than 1 user in 1000
Rare: affects more than 1 user in 10,000

- **Common:**
  Headache, diarrhoea, constipation, abdominal pain, nausea, vomiting and flatulence
- **Uncommon:**
  Dizziness, loss of sensation, somnolence, insomnia and vertigo, increased levels of liver enzymes, hives or 'pins and needles', itchy skin, feeling generally unwell.
- **Rare:**
  Reversible mental confusion, agitation, aggressiveness, depressionand hallucinations mainly in seriously ill patients
  Enlarged breasts in men
  Dry mouth, inflammation inside the mouth and gastrointestinal thrush
  Reduced number of white cells or platelets, changes in blood count including agranulocytosis (lack of white blood cells), insufficient formation of blood cells Brain damage in patients with persistent serious liver disorders, hepatitis with or without jaundice, liver failure
  Joint pain, muscular pain and weakness
  Light sensitivity, allergic reactions, Erythema multiforme (Stevens-Johnson syndrome), skin peeling or blistering and alopecia
  Hypersensitivity reactions such as severe rash, fever, bronchospasm, kidney disorder and anaphylactic shock. Increased sweating, peripheral oedema, blurred vision, taste changes and deficient levels of sodium salts in the blood

Isolated cases of irreversible visual impairment have been recorded in seriously ill patients treated with intravenous bolus injections of Gastrisec, particularly at high doses, but no causal relationship has been proved.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE GASTRISEC 40 mg

Keep out of the reach and sight of children.

Do not use Gastrisec 40 mg after the expiry date which is stated on the label and package. The expiry date refers to the last day of the month shown.

Do not store above 25 ºC.

Store in the original package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines and packages no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What GASTRISEC 40 mg contains
The active ingredient is Gastrisec (sodium salt). Each vial contains 40 milligrams of omeprazole (sodium). The other ingredients are: sodium hydroxide.
Product appearance
White lyophilised powder.
Gastrisec 40 mg comes in 10 ml vials.

Manufacturer:
Laboratorio Reig Jofré, S.A.
Gran Capitán, 10
08970 Sant Joan Despí (Barcelona)
SPAIN

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This information is intended solely for doctors or healthcare professionals:
The lyophilisate must only be reconstituted by dissolving it in 100 ml of 5% glucose solution.
Its chemical and physical stability in conditions of use has been confirmed for 6 hours following preparation dissolved in 5% glucose solution.
From the microbiological perspective, the product must be used immediately unless it has been reconstituted in controlled and validated aseptic conditions.No special precautions are required for its handling in normal lighting conditions.

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