

Package leaflet: Information for the user

Gastrimut® 40 mg hard gastro-resistant capsules Omeprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Gastrimut® 40 mg is and what it is used for

Gastrimut® 40 mg contains the active substance omeprazole. It belongs to a group of medicines called “proton pump inhibitors”. These medicines work by reducing the amount of acid that your stomach produces.

Gastrimut® 40 mg is used to treat the following conditions:

In adults:

- “Gastroesophageal reflux disease” (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers which are infected with bacteria called “*Helicobacter pylori*”. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Gastrimut® 40 mg can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- “Gastroesophageal reflux disease” (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn. In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), vomiting and poor weight gain.

Children over 4 years of age and adolescents

- Ulcers which are infected with bacteria called “*Helicobacter pylori*”. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. What you need to know before you take Gastrimut® 40 mg

Do not take Gastrimut® 40 mg

- If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors (e.g., pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (used for HIV infection).

Do not take Gastrimut® 40 mg if you experience any of the previous cases.

If you are not sure, talk to your doctor or pharmacist before taking Gastrimut® 40 mg.

Warnings and precautions

Gastrimut® 40 mg may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Gastrimut® 40 mg or while you are taking it, talk to your doctor immediately:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained feces).
- You experience severe or persistent diarrhea, as omeprazole has been associated with a small increase in infectious diarrhea.
- You have severe liver problems.
- You have ever had a skin reaction after treatment with a medicine like omeprazole that reduces stomach acid.

Before taking this medicinal product, tell your doctor if:

- It is planned that you are going to have a specific blood test (Chromogranin A).

If you take omeprazole on a long-term basis (longer than 1 year), your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking a proton pump inhibitor like omeprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If you get a skin rash, especially in sun-exposed skin areas, tell your doctor as soon as you can, as you may need to stop your treatment with omeprazole. Remember to also mention any other symptoms, like pain in your joints.

Other medicines and Gastrimut® 40 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. This is because omeprazole can affect the way some medicines work, and some medicines can have an effect on omeprazole.

Do not take omeprazole if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).

- Digoxin (used to treat heart problems).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking omeprazole .
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking omeprazole .
- Rifampicin (used to treat tuberculosis).
- Atazanavir (used to treat HIV infection).
- Tacrolimus (in cases of organ transplantation).
- St John's wort (*Hypericum perforatum*) (used to treat mild depression).
- Cilostazol (used to treat intermittent claudication).
- Saquinavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots (thrombi)).
- Erlotinib (used to treat cancer).
- Methotrexate (a chemotherapy drug used in high doses to treat cancer) - if you are taking a high dose of methotrexate, your doctor will temporarily stop your treatment with omeprazole.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as omeprazole to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Gastrimut® 40 mg with food and drink

You can take your capsules with food or on an empty stomach.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Although omeprazole passes into breast milk, it is unlikely that a risk to infants occurs if administered at therapeutic doses. Your doctor will decide whether you can take omeprazole if you are breast-feeding.

Driving and using machines

Omeprazole is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Gastrimut® 40 mg contains sucrose

This medicine contains sucrose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Gastrimut® 40 mg

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are.

The usual doses are given below.

Adults:

To treat symptoms of GERD, such as **heartburn** and **acid regurgitation**:

- If your doctor has found that your gullet has been slightly damaged, the recommended dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is 10 mg once a day.
- If your gullet has not been damaged, the recommended dose is 10 mg once a day.

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take that same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat **ulcers in the stomach** (gastric ulcer):

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take that same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To **prevent the duodenal and stomach ulcers** from coming back:

- The recommended dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat **duodenal and stomach ulcers caused by NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs):

- The recommended dose is 20 mg once a day for 4-8 weeks.

To **prevent duodenal and stomach ulcers** if you are taking **NSAIDs**:

- The recommended dose is 20 mg once a day.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- The recommended dose is 20 mg Gastrimut® 40 mg twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat too much acid in the stomach caused by a **growth in the pancreas (Zollinger-Ellison syndrome)**:

- The recommended dose is 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Children:

To treat symptoms of GERD, such as **heartburn** and **acid regurgitation**:

- Children over 1 year of age and with a body weight of more than 10 kg can take omeprazole. The dose for children is based on the child's weight, and the doctor will decide the correct dose.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- Children aged over 4 years may take Gastrimut® 40 mg. The dose for children is based on the child's weight, and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

How to take this medicine

- It is recommended that you take your capsules in the morning.
- You can take your capsules with food or on an empty stomach.

- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you or your child have trouble swallowing the capsules

- If you or your child have trouble swallowing the capsules:
 - Open the capsules and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, any acidic fruit juice (e.g., apple, orange or pineapple) or apple sauce.
 - Always stir the mixture just before drinking it (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes.
 - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.

If you take more Gastrimut® 40 mg than you should

In the event of an overdose or accidental ingestion, call your doctor or pharmacist immediately.

In case of overdose or accidental ingestion, contact your doctor or pharmacist at once or go to the nearest hospital, indicating the medicine and the amount received.

If you forget to take Gastrimut® 40 mg

If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

If you notice any of the following rare but serious side effects, stop taking Gastrimut® 40 mg and contact a doctor immediately:

- Sudden wheezing when breathing, swelling of your lips, tongue and throat or body, skin rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be “Stevens-Johnson syndrome” or “toxic epidermal necrolysis”.
- Yellow skin, dark urine and tiredness, which can be symptoms of liver problems.

Other side effects include:

Common side effects (may affect up to 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhea, stomach pain, constipation and wind (flatulence).
- Nausea or vomiting.
- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings, feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

Rare side effects (may affect up to 1 in 1,000 people)

- Blood problems, such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever and wheezing.
- Low levels of sodium in the blood. This may cause weakness, vomiting and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Visual problems, such as blurred vision.
- Suddenly feeling short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called “thrush”, which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice, which can cause yellow skin, dark urine and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects (may affect up to 1 in 10,000 people)

- Changes in blood count, including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Enlarged breasts in men.

Not known frequency (cannot be estimated from the available data)

- Gut inflammation (which causes diarrhea).
- If you are on Gastrimut® 40 mg hard gastro-resistant capsules for more than three months, it is possible that your blood magnesium levels may fall. Low levels of magnesium can cause fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor immediately. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- Rash, possibly with pain in the joints.

Omeprazole may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection, such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about the medicine you are taking currently.

Reporting of side effects

If you get any adverse effects talk to your doctor, pharmacist or nurse. This includes any possible adverse effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gastrimut® 40 mg

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

PVC-PVDC/Aluminum blister: Store below 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines and packages you no longer need. These measures will help protect the environment.

6. Contents of the pack and other information

What Gastrimut® 40 mg contains

- The active substance is omeprazole. Gastrimut® 40 mg capsules contain 40 mg of omeprazole.
- The other ingredients (excipients) are sugar spheres (sucrose and maize starch), hypromellose, talc, titanium dioxide (E-171), disodium hydrogen phosphate dihydrate, copolymer of methacrylic acid and ethyl acrylate (sodium lauryl sulfate, Polysorbate 80) and triethyl citrate. The gelatin capsule is composed by titanium dioxide (E-171), indigotine (E-132), quinoline yellow (E-104) and gelatin.

What Gastrimut® 40 mg looks like and contents of the pack

Gastrimut® 40 mg capsules have a body and a green opaque cap.

Gastrimut® 40 mg is supplied in hard gelatin capsules, which contain gastro-resistant microgranules of omeprazole, in packs containing 14, 28 and 56 capsules.

Not all pack sizes may be marketed in all countries.

Marketing Authorisation Holder and Manufacturer

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