

Package leaflet: Information for the user
Esomeprazole 20 mg gastro-resistant capsules, hard
Esomeprazole 40 mg gastro-resistant capsules, hard
Esomeprazole

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Esomeprazole gastro-resistant capsules are and what they are used for
2. What you need to know before you take Esomeprazole gastro-resistant capsules
3. How to take Esomeprazole gastro-resistant capsules
4. Possible side effects
5. How to store Esomeprazole gastro-resistant capsules
6. Contents of the pack and other information

1. What Esomeprazole gastro-resistant capsules are and what they are used for

Esomeprazole gastro-resistant capsules contain a medicine called esomeprazole, which belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Esomeprazole gastro-resistant capsules are used to treat the following conditions:

Adults and adolescents aged 12 years and above

- '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 stomach or upper part of the gut (intestine) that 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.

Adults

- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole gastro-resistant capsules can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole.

2. What you need to know before you take Esomeprazole gastro-resistant capsules

Do not take Esomeprazole gastro-resistant capsules:

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

Do not take Esomeprazole gastro-resistant capsules if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Esomeprazole gastro-resistant capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking Esomeprazole gastro-resistant capsules:

- if you have severe liver problems.
- if you have severe kidney problems.
- if you have ever had a skin reaction after treatment with a medicine similar to Esomeprazole gastro-resistant capsules that reduces stomach acid.
- if you are due to have a specific blood test (Chromogranin A).

Esomeprazole gastro-resistant capsules may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Esomeprazole gastro-resistant capsules or while you are taking them, talk to your doctor straight away:**

- 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 faeces).

Taking a proton pump inhibitor like Esomeprazole gastro-resistant capsules, 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).

This medicine may affect the way that your body absorbs vitamin B₁₂, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B₁₂:

- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression.

Rash and skin symptoms

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Esomeprazole gastro-resistant capsules. Remember to also mention any other ill-effects like pain in your joints.

Serious skin rashes have occurred in patients taking esomeprazole (see also section 4). The rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes often come after flu-like symptoms such as fever, headache, body ache. The rash may cover large parts of the body with blistering and peeling of the skin.

If at any time during the treatment (even after several weeks) you develop a rash or any of these skin symptoms, stop taking this medicine and contact your doctor immediately.

If you have been prescribed Esomeprazole gastro-resistant capsules “on demand” you should contact your doctor if your symptoms continue or change in character.

Talk to your doctor, pharmacist or nurse before taking Esomeprazole gastro-resistant capsules.

Other medicines and Esomeprazole gastro-resistant capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription. This is because Esomeprazole gastro-resistant capsules can affect the way some medicines work and some medicines can have an effect on Esomeprazole gastro-resistant capsules.

Do not take Esomeprazole gastro-resistant capsules 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:

- Atazanavir or saquinavir (used to treat HIV infection).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- Citalopram, imipramine or clomipramine (used to treat depression).
- 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 Esomeprazole gastro-resistant capsules.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Esomeprazole gastro-resistant capsules.
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Cisapride (used for indigestion and heartburn).
- Digoxin (used for heart problems).
- Clopidogrel (used to treat or prevent blood clots).
- Tacrolimus (organ transplantation).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Esomeprazole gastro-resistant capsules treatment).
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

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

Esomeprazole gastro-resistant capsules 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. Your doctor will decide whether you can take Esomeprazole gastro-resistant capsules during this time.

It is not known if Esomeprazole gastro-resistant capsules pass into breast milk. Therefore, you should not take Esomeprazole gastro-resistant capsules if you are breast-feeding.

Driving and using machines

Esomeprazole gastro-resistant capsules are not likely to affect your ability to drive or use any tools or machines. However, side effects such as dizziness and blurred vision may uncommonly or rarely occur (see section 4). If affected, you should not drive or use machines.

Esomeprazole gastro-resistant capsules contain sucrose, benzoic acid and sodium

Esomeprazole gastro-resistant capsules contain sucrose, which is a type of sugar, and benzoic acid (E210):

- If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine,
- This medicine contains 1.80 micrograms of benzoic acid in each 20 mg dosage unit.
This medicine contains 3.50 micrograms of benzoic acid in each 40 mg dosage unit.

Sodium content

Esomeprazole gastro-resistant capsules contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Esomeprazole gastro-resistant capsules

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

- Esomeprazole gastro-resistant capsules are not recommended for children less than 12 years old.
- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

Taking this medicine

- You can take your capsules at any time of the day.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with a glass of water. Do not chew or crush the capsules or their contents. This is because the capsules contain coated granules which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the granules.

What to do if you have trouble swallowing the capsules

- If you have trouble swallowing the capsules:
 - 1) Open the capsule carefully above a glass of still (non-fizzy) water and empty the content of the capsule (granules) into the glass. Do not use any other liquids.
 - 2) Stir. Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
 - 3) 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 cannot swallow at all, the content of the capsule can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ('gastric tube').

How much to take

- 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 well your liver works.
- The recommended doses are given below.

To treat heartburn caused by gastroesophageal reflux disease (GERD):

Adults and children aged 12 or above:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one capsule of Esomeprazole gastro-resistant capsules 40 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is one capsule of Esomeprazole gastro-resistant capsules 20 mg once a day.
- If your gullet has not been damaged, the recommended dose is one capsule Esomeprazole gastro-resistant capsules 20 mg each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one capsule of Esomeprazole gastro-resistant capsules 20 mg each day.
- If you have severe liver problems, your doctor may give you a lower dose.

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

Adults and children aged 12 or above:

- The recommended dose is one capsule of Esomeprazole gastro-resistant capsules 20 mg twice a day for one week.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

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

Adults aged 18 and above:

- The recommended dose is one capsule of Esomeprazole gastro-resistant capsules 20 mg once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

Adults aged 18 and above:

- The recommended dose is one capsule of Esomeprazole gastro-resistant capsules 20 mg once a day.

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

Adults aged 18 and above:

- The recommended dose is one capsule of Esomeprazole gastro-resistant capsules 40 mg twice a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. The maximum dose is 80 mg twice a day.

Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole:

The recommended dose is one capsule of Esomeprazole gastro-resistant capsules 40 mg once a day for 4 weeks.

Children under the age of 12 years

Esomeprazole gastro-resistant capsules are not recommended for children less than 12 years old.

Elderly

Dose adjustment is not required in the elderly.

If you take more Esomeprazole gastro-resistant capsules than you should

If you take more Esomeprazole gastro-resistant capsules than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Esomeprazole gastro-resistant capsules

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 serious side effects, stop taking Esomeprazole gastro-resistant capsules and contact a doctor immediately:

- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. These effects are rare, and may affect up to 1 in 1,000 people.
- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction). These effects are rare, and may affect up to 1 in 1,000 people.
- Sudden onset of a severe rash or reddening of the skin with blisters or peeling may occur even after several weeks of treatment. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life threatening

consequences. This could be ‘erythema multiforme’, ‘Stevens-Johnson syndrome’, ‘toxic epidermal necrolysis’ or ‘drug reaction with eosinophilia and systemic symptoms’. These effects are very rare, and might affect up to 1 in 10,000 people.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach.

Uncommon (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy.
- Spinning feeling (vertigo).
- Dry mouth.
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Fracture of the hip, wrist or spine (if Esomeprazole gastro-resistant capsules are used in high doses and over long duration).

Rare (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.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- 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).
- Generally feeling unwell and lacking energy.
- Increased sweating.

Very rare (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, drug reaction with eosinophilia and systemic symptoms).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

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

- If you are on Esomeprazole gastro-resistant capsules for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased

heart rate. If you get any of these symptoms, please tell your doctor promptly. 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.

- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

Esomeprazole gastro-resistant capsules 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 your medication at this time.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esomeprazole gastro-resistant capsules

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Keep this medicine in the original container (blister) or keep the container tightly closed (bottle) in order to protect from moisture.
- Do not use this medicine after the expiry date shown on the carton or bottle or blister foil. The expiry date refers to the last day of that month.
- After opening of the bottle, the capsules should be used within 3 months.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Esomeprazole gastro-resistant capsules contain

- The active substance is esomeprazole.
Esomeprazole gastro-resistant capsules come in two strengths containing 20 mg or 40 mg of esomeprazole (as magnesium dihydrate).
- The other ingredients are:
Capsule content:
sugar spheres (sucrose and maize starch), hypromellose, simethicone emulsion 30% (containing simethicone, polyoxyethylene sorbitan tristearate (polysorbate 65) (E436), methylcellulose, polyethylene glycol stearate, glycerides, xanthan gum, benzoic acid (E210), sorbic acid (E200), sulfuric acid), polysorbate 80, mannitol, diacetylated monoglycerides, talc, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 % (containing copolymer of methacrylic acid and ethyl acrylate, sodium lauryl sulfate and polysorbate 80), triethyl citrate and stearyl macroglycerides.
Capsule shell:
gelatin, yellow iron oxide (E 172) and titanium dioxide (E 171)
Printing ink:
black iron oxide (E 172), shellac, ammonia, propylene glycol, potassium hydroxide.

What Esomeprazole gastro-resistant capsules look like and contents of the pack

- 20 mg capsules have an opaque yellow cap and an opaque white body. “20 mg” is printed in black both on the cap and on the body.

- 40 mg capsules have an opaque yellow cap and an opaque yellow body. “40 mg” is printed in black both on the cap and on the body.
- Your capsules will come in packs of:
Bottles of 28, 30, 90 or 98 capsules
Blisters of 3, 7, 14, 15, 25, 28, 30, 50, 56, 60, 90, 98, 100 or 140 capsules
Not all pack size may be marketed.

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