

Package leaflet: Information for the patient
Esomeprazole 20 mg Gastro-Resistant Tablets
Esomeprazole 40 mg Gastro-Resistant Tablets
(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 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.

What is in this leaflet

1. What Esomeprazole is and what it is used for
2. What you need to know before you take Esomeprazole
3. How to take Esomeprazole
4. Possible side effects
5. How to store Esomeprazole
6. Contents of the pack and other information

1. What Esomeprazole is and what it is used for

The name of your medicine is Esomeprazole Gastro-Resistant Tablets. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Esomeprazole is used to treat the following conditions:

Adults and Adolescents aged 12 years and over

- 'Gastro-oesophageal reflux disease' (GORD). 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). This medicine 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

Do not take this medicine:

- If you are allergic to esomeprazole, or to 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 infection).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Esomeprazole.

Warnings and precautions

Talk to your doctor or pharmacist before taking Esomeprazole:

- 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 that reduces stomach acid.
- If you are due to have a specific blood test (Chromogranin A)

Esomeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking this medicine or while you are taking it, 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).

If you have been prescribed Esomeprazole "on demand" you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like this medicine, 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).

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. 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.

Children under the age of 12 years

For children aged 1 to 11 years, another formulation such as sachet with granules for oral suspension can be used (ask your doctor or pharmacist if you require further information).

Other medicines and Esomeprazole

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 Tablets can affect the way some medicines work and some medicines can have an effect on Esomeprazole Gastro-Resistant Tablets.

Do not take Esomeprazole Tablets 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 (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots).
- 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 this medicine.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking this medicine.
- 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).
- 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 treatment.
- Tacrolimus (organ transplantation).
- 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 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 with food and drink

You can take your tablets 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 this during this time.

It is not known if this passes into breast milk. Therefore, you should not take Esomeprazole if you are breastfeeding.

Driving and using machines

Esomeprazole is not likely to affect you being able 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 Tablets contains sucrose and lactose

Esomeprazole gastro-resistant tablets contain sucrose and lactose as type of sugars. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Esomeprazole

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

- 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.

How much to take

- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition, how old you are and how well your liver works.
- The recommended doses are given below.

To treat heartburn caused by gastro-oesophageal reflux disease (GORD):

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 Esomeprazole 40 mg gastro-resistant tablet 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 Esomeprazole 20 mg gastro-resistant tablet once a day
- If your gullet has not been damaged, the recommended dose is one Esomeprazole 20 mg gastro-resistant tablet 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 Esomeprazole 20 mg gastro-resistant tablet 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 young people aged 12 or above: the recommended dose is one Esomeprazole 20 mg gastro-resistant tablet twice a day for one week.
- Your doctor will also tell you to take antibiotics for example 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 Esomeprazole 20 mg gastro-resistant tablet 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 Esomeprazole 20 mg gastro-resistant tablet 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 Esomeprazole 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 re-bleeding of ulcers with intravenous Esomeprazole:

- Adults aged 18 and above: the recommended dose is one Esomeprazole 40 mg tablet once a day for 4 weeks.

Taking this medicine

- You can take your tablets at any time of the day.
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets. This is because the tablets 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 have trouble swallowing the tablets

- If you have trouble swallowing the tablets:
 - Put them into a glass of still (non-fizzy) water. Do not use any other liquids
 - Stir until the tablets break up (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
 - 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 tablet 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').

Children under the age of 12 years

Esomeprazole gastro-resistant tablets 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 tablets than you should

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

If you forget to take Esomeprazole gastro-resistant tablets

- 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 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 this medicine and contact a doctor immediately:

- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. These effects are rare, which 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, which may affect up to 1 in 1,000 people.
- Sudden onset of severe rash or reddening of the skin with blisters or peeling. 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 is 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 this medicine 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 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 effect, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly at: www.hpra.ie or E-mail: medsafety@hpra.ie for Ireland. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esomeprazole

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- 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 tablets contains

- The active substance is Esomeprazole (as magnesium dihydrate)
20 mg: Each gastro-resistant tablet contains 20 mg of esomeprazole (as magnesium dehydrate)
40 mg: Each gastro-resistant tablet contains 40 mg of esomeprazole (as magnesium dihydrate)

The other ingredients are sugar spheres (sucrose and maize starch), hypromellose, silicified microcrystalline cellulose, lactose monohydrate, maize starch, meglumine, poloxamer 188, sodium lauryl sulfate, methacrylic acid copolymer, triethyl citrate, glyceryl monostearate, talc, sodium hydroxide, hydroxy propyl cellulose, macrogol, crospovidone, silica colloidal, magnesium stearate, opadry pink 13G84577 (consists of hypromellose, titanium dioxide (E171), macrogol, talc, paraffin light liquid, polysorbate 80, iron oxide red (E172), iron oxide yellow (E172)), opadry pink 13G84576 (consists of hypromellose, titanium dioxide (E171), macrogol, talc, paraffin light liquid, polysorbate 80, iron oxide red (E172), iron oxide yellow (E172)) (see section 2 under 'Esomeprazole gastro-resistant tablets contains sucrose and lactose').

What Esomeprazole gastro-resistant tablets looks like and contents of the pack

- 20 mg: Light pink colored oval shaped, bevel edged tablets debossed with 'H' on one side and '186' on the other side. The tablet dimensions are 14.2mm x 7.1mm.
- 40 mg: Pink colored oval shaped, bevel edged tablets debossed with 'H' on one side and '187' on the other side. The tablet dimensions are 16.2mm x 8.1mm.
- Esomeprazole gastro-resistant tablets are available in the below pack sizes:
Alu- Alu blister packs 3, 7, 7x1, 14, 15, 25x1, 28, 30, 50, 50x1, 56, 60, 90, 98, 100x1, 100, 140 tablets. Not all pack sizes may be marketed.

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This medicinal product is authorised in the Member States of the EEA under the following names:

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