Package leaflet: Information for the patient

Esomeprazole gastro-resistant hard capsules 20 mg
Esomeprazole gastro-resistant hard capsules 40 mg

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 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 or 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 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

Esomeprazole contains a medicine called esomeprazole. 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
- '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.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole 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.

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.

2. What you need to know before you take Esomeprazole

Do not take Esomeprazole
- 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 or rilpivirine (used to treat HIV infection). If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking esomeprazole or other related medicines.

Do not take Esomeprazole 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 Esomeprazole 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 Esomeprazole, 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 reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported in association with Esomeprazole treatment. Stop using Esomeprazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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 can affect the way some medicines work and some medicines can have an effect on Esomeprazole.

Do not take Esomeprazole if you are taking a medicine containing nelfinavir or rilpivirine (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 treat or 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 Esomeprazole.
- 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.
- 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).
- 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 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 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 capsules with food or on an empty stomach.

Pregnancy, breast-feeding and fertility
If you are pregnant, 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 during this time. It is not known if Esomeprazole 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 contains sucrose, sodium and benzoic acid

<u>Sucrose</u>
Esomeprazole contains sugar spheres which contain sucrose, a type of sugar**.** If you have been

told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

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

Benzoic acid
This medicine contains 0.02 micrograms of benzoic acid in each dosage unit containing 20 mg of esomeprazole.
This medicine contains 0.04 micrograms of benzoic acid in each dosage unit containing 40 mg of esomeprazole.

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 capsules 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.

Adults aged 18 and above
To treat heartburn caused by gastro-oesophageal reflux disease (GERD):
- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one capsule of Esomeprazole 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 20 mg once a day.
- If your gullet has not been damaged, the recommended dose is one capsule Esomeprazole 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 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:
- The recommended dose is one capsule of Esomeprazole 20 mg 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):
- The recommended dose is one capsule of Esomeprazole 20 mg once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):
- The recommended dose is one capsule of Esomeprazole 20 mg once a day.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):
- The recommended dose is one capsule of 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 rebleeding of ulcers with intravenous Esomeprazole:
The recommended dose is one capsule of Esomeprazole 40 mg once a day for 4 weeks.

Children under the age of 12 years
Esomeprazole is not recommended for children less than 12 years old.

Use in adolescents aged 12 or above

To treat heartburn caused by gastroesophageal reflux disease (GERD):
- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one capsule of Esomeprazole 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 20 mg once a day.
- If your gullet has not been damaged, the recommended dose is one capsule of

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

Elderly
Dose adjustment is not required in the elderly.

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’).

If you take more Esomeprazole than you should
If you take more Esomeprazole than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Esomeprazole
- 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 may cause side effects, although this may not be the case. occur in everyone.

If you notice any of the following serious side effects, stop taking Esomeprazole 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' . These effects are very rare, and might affect up to 1 in 10,000 people.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). These effects are very rare, and might affect up to 1 in 10,000 people.

Other side effects include:

<u>Common (may affect up to 1 in 10 people)</u>

- 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.

<u>Uncommon (may affect up to 1 in 100 people)</u>

- 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).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)
- If you are on Esomeprazole 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, 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 effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. 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 use this medicine after the expiry date which is stated on the carton or bottle or blister foil after EXP. The expiry date refers to the last day of that month.
- For Blister pack: Do not store above 25°C. Store in the original package in order to protect from moisture.
- For Bottle Pack: This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.
- 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. Content of the pack and other information

What Esomeprazole contains

20 mg: The active substance is esomeprazole. Each gastro-resistant capsule contains 22,25 mg esomeprazole trihydrate equivalent to 20 mg esomeprazole.

40 mg: The active substance is esomeprazole. Each gastro-resistant capsule contains 44,5 mg esomeprazole trihydrate equivalent to 40 mg esomeprazole.

• The other ingredients are:
Capsule content: Glycerol monostearate, Hydroxy propyl cellulose (Hydroxy propyl cellulose and Silica, Colloidal Anhydrous), Hypromellose 2910, Magnesium stearate, Polysorbate 80, Sugar spheres (Maize Starch, Sucrose), Talc, Triethyl citrate, Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion -[containing Methacrylic acid - ethyl acrylate copolymer (1:1), Sodium Laurilsulfate, Simeticone, Polysorbate 80], Simeticone (emulsion)- [containing Simeticone, Polyoxyethylene Sorbitan Tristearate, Methylcellulose, Poly (ethylene oxide) stearate, Glyceryl stearate, Xanthan Gum, Benzoic Acid, Sorbic Acid, Sulfuric Acid]

Capsule shell: Gelatin, Titanium dioxide (E171), Sodium lauryl sulphate, Sorbitan Monolaurate, Brilliant Blue FCF – (only in 20 mg), Printing Ink [containing Shellac and Black iron oxide (E172)]

What Esomeprazole looks like and contents of the pack

20 mg: Off white to pale brown colored pellets filled in blue opaque hard gelatin capsules imprinted with “G” on cap and ‘59” on the body. The actual size of the capsule is length 13.5 – 15.0 mm x width 5.0 – 5.6 mm.

40 mg: Off white to pale brown colored pellets filled in white opaque hard gelatin capsules imprinted with “G” on cap and ‘60” on the body. The actual size of the capsule is length 15.0 – 17.5 mm x width 5.5 – 6.1 mm.

Pack details
< Product name > is available in Alu-OPA/ALU/PVC blister pack containing 7, 14, 15, 28, 30, 56, 60, 90 and 98 capsules.

< Product name > is available in HDPE bottle with polypropylene child-resistant closure pack containing 28, 30 and multipacks containing90 (3 bottle packs of 30’s count (3x30) in one carton) capsules.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer:

Marketing Authorization Holder:
PharmConsul s.r.o.
Krcmarovska 223/33
Miskovice
Prague
19600
Czechia

Manufacturer:

Pharmazet Group s.r.o.
Trtinova 260/1
Cakovice
Prague
19600
Czechia

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The following information is intended for healthcare professionals only:

Administration through Nasogastric tube (NG tube)
The suspension can be given only through a nasogastric tube size 8 Fr or larger.

1. Open the capsule and empty the granules into a 60 mL catheter tipped syringe.
2. Mix with 50 mL of drinking water.
3. Use only a catheter tipped syringe to give esomeprazole magnesium delayed-release capsules through a NG tube.
4. Replace the plunger and shake the syringe well for 15 seconds.
5. Hold the syringe with the tip up and check for any granules remaining in the tip.
6. Do not give the granules if they have dissolved or have broken into pieces.
7. Attach the syringe to the NG tube. Give the medicine right away in the syringe through the NG tube into the stomach.

8. After giving the granules, fill the syringe with 20 ml of water and repeat step 5 if necessary to wash down any sediment left in the syringe to flush the NG tube.

Any unused product or waste material should be disposed of in accordance with local requirements.