

Package leaflet: Information for the user

Esomeprazole 40mg powder for solution for injection or infusion

Esomeprazole

Read all of this leaflet carefully before you start using 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.

What is in this leaflet

1. What Esomeprazole is and what it is used for
2. What you need to know before you use Esomeprazole
3. How to use Esomeprazole
4. Possible side effects
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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 for the short term treatment of certain conditions, when you are unable to have treatment by mouth. It is used to treat:

- '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.
- 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.
- Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

2. What you need to know before you use Esomeprazole

You must not be given Esomeprazole if:

- you are allergic to esomeprazole or any of the other ingredients of this medicine (listed in Section 6).
- you are allergic to other proton pump inhibitor medicines.
- you are taking a medicine containing nelfinavir (used to treat HIV).
- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Esomeprazole or other related medicines.

You must not be given Esomeprazole if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Talk to your doctor or nurse before you are given Esomeprazole if:

- you have severe liver problems.
- you have severe kidney problems.

Esomeprazole may hide the symptoms of other diseases. Therefore, **if any of the following symptoms happen to you before or after you are given Esomeprazole, talk to your doctor straight away:**

- If your weight decreases for no reason and you have problems in swallowing.
- If you get stomach pains or indigestion.
- If you begin to vomit food or blood.
- If you pass black stools (blood-stained faeces).

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).

Talk to your doctor before taking Esomeprazole:

- 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).

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 nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Esomeprazole can affect the way some medicines work and some medicines can have an effect on Esomeprazole.

You must not be given Esomeprazole if you are taking a medicine containing nelfinavir (used to treat HIV).

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

- Atazanavir (used to treat HIV).
- 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 being given 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).
- 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.
- Rifampicine (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop being given Esomeprazole.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine. Your doctor will decide whether you can be given Esomeprazole during this time.

It is not known if Esomeprazole passes into breast milk. Therefore, you should not be given 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.

Esomeprazole contains sodium

This medical product contains 1 mmol sodium (17 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Esomeprazole

Esomeprazole can be given to children and adolescents under 18 years of age, and adults, including elderly people.

Being given Esomeprazole

Esomeprazole will be given to you by a doctor who will decide how much you need.

The usual dose is 20 mg or 40 mg, once a day.

If you have severe liver problems, the maximum dose is 20 mg a day (for GORD).

The medicine will be given to you as an injection or infusion into one of your veins. This will last for up to 30 minutes.

For prevention of rebleeding gastric or duodenal ulcers, the usual dose is 80 mg administered as an infusion into one of your veins over 30 minutes followed by a continuous infusion of 8 mg/hr given over 3 days. If you have severe liver problems, a continuous infusion of 4 mg/hr given over 3 days may be sufficient.

Children aged 1-18 years

Esomeprazole Ticerin will be given by your doctor who will decide how much you need.

For children 1-11 years, the recommended dose is 10 or 20 mg given once a day.

For children 12-18 years, the recommended dose is 20 or 40 mg given once a day.

The medicine will be given as an injection or infusion into a vein. This will last up to 30 minutes.

If you are given more Esomeprazole than you should

If you think you have been given too much Esomeprazole, talk to your doctor straight away.

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

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 and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, 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. These effects are rare, affecting less than 1 in 1,000 people.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome), seen very rarely.

Other side effects include:

Common (affects less than 1 in 10 people)

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

Uncommon (affects less than 1 in 100 people)

- Swelling of the legs and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings, paresthesias (sensitivity changes), feeling sleepy.
- Spinning feeling (vertigo).
- Eyesight problems such as blurred vision.
- Dry mouth.
- Changes in blood tests that check how the liver is working.
- Skin rash, hives and itchy skin.

Rare (affects less than 1 in 1,000 people)

- Blood changes 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.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Inflammation of the inside of the mouth.
- 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 (affects less than 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.

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.

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.
- Rash, possibly with pain in the joints.

Do not be concerned by this list of possible side effects.

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:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail:

medsafety@hpra.ie

5. How to store Esomeprazole

The doctor and hospital pharmacist are responsible for storing, using and disposing of Esomeprazole correctly.

Do not use this medicine after the expiry date (EXP) shown on the carton or vial. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Keep the vial in the outer carton in order to protect from light.

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 contains

- The active substance is esomeprazole. Each vial of powder for solution for injection/infusion contains 42.5 mg of esomeprazole sodium, equivalent to 40 mg of esomeprazole.
- The other ingredients are disodium edetate and sodium hydroxide.

What Esomeprazole looks like and content of the pack

Esomeprazole 40 mg powder for solution for injection or infusion is a white to off-white powder, with a porous and uniform appearance. This is prepared into a solution before it is given to you.

The product is packed in Type I glass vials, sealed with a stopper made of bromobutyl rubber, cap made of aluminium and a plastic polypropylene lid, in packs containing 1 and 10 units. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Laboratórios Azevedos – Indústria Farmacêutica, S.A.
Estrada Nacional 117-2, Alfragide
2614-503 Amadora
Portugal

Manufacturer

Sofarimex – Indústria Química e Farmacêutica, S.A.
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2735-213 Cacém
Portugal

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