



esomeprazole

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed 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
5. How to store Esomeprazole
6. Contents of the pack and other information

- 'Gastro-oesophageal reflux disease' (GORD) in adults, adolescents and children. 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 in adults 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 in adults following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

- If you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of this medicine (listed in Section 6: Further information).
- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).

- Atazanavir (used to treat HIV infection).
- Ketoconazole, itraconazole or voriconazole (used to treat fungal infections).
- 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 having esomeprazole.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop having 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).
- Clopidogrel (used for prevention of blood clots).
- 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.

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).



Esomeprazole 40 mg contains 42.5 mg esomeprazole sodium equivalent to 40 mg esomeprazole. Each vial also contains disodium edetate and sodium hydroxide (<1 mmol sodium).

For the reconstitution of solution, withdraw the coloured plastic cap at the top of the vial of Esomeprazole, and pierce the stopper in the centre of the designed circle, by maintaining the needle vertically, in order to be able to cross the stopper correctly.

The shelf life after reconstitution in terms of chemical and physical stability has been demonstrated for 12 hours at 30°C. However, from a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.



Hospira

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- 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.

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).
- Injection site reaction.

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).
- Eyesight problems such as blurred vision.
- 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.
- 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 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).

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.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
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 sight and reach of children.
- Store below 25°C.
- Store in the original package, in order to protect from light.

After reconstitution

Chemical and physical in-use stability has been demonstrated for 12 hours at 30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Do not use this medicine if you notice visually particulate matter and discoloration prior to administration after reconstitution.

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 sodium. 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 (for pH adjustment).

What Esomeprazole looks like and contents of the pack

Esomeprazole is a white to off-white ‘cake’ or powder. It is supplied in a glass vial. This is made into a solution before it is given to you.

Pack sizes: 1 vial, 1 x 5 vials, 1 x 10 vials, 1 x 25 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Hospira UK Limited
Queensway
Royal Leamington Spa
Warwickshire
CV31 3RW
United Kingdom

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Esomeprazole Injection

To prepare a solution for injection:

Injection 40 mg

For 8 mg/ml esomeprazole reconstituted solution: Prepare the solution by adding 5 ml of 0.9% (9 mg/ml) sodium chloride for intravenous use to the esomeprazole 40 mg vial.

The reconstituted solution for injection should be administered intravenously over a period of at least 3 minutes.

For further information on dose administration, please see SmPC section 4.2.

Esomeprazole Infusion

To prepare a solution for infusion:

Infusion 40 mg

Dissolve the content of one esomeprazole 40 mg vial in up to 100 ml of 0.9% (9 mg/ml) sodium chloride for intravenous use.

Infusion 80 mg

Dissolve the contents of two esomeprazole 40 mg vials in up to 100 ml of 0.9% (9 mg/ml) sodium chloride for intravenous use.

For further information on dose administration, please see SmPC section 4.2.

Disposal

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

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LEA-xxxxxx-00

Component Specification	
Item number:	Q74030
Request number:	AS2236
Country:	United Kingdom
OI template:	OCI005
Amalia version:	1
Mulgrave version:	N/A
Dimensions:	295 x 350 mm
Container(s):	vial
Supplier:	Gland Pharma India
Stock:	Bible paper 40 gsm±10% tbc
Folded dimensions:	tbc
Printed both sides:	Yes
Perforated:	No
Pharma code:	N/A
Pharma code length:	N/A
Supplier Code:	TBC
Colours	
Black:	■



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