Package leaflet: Information for the user
Esomeprazole 40 mg Powder for Solution for Injection/Infusion
esomeprazole (as sodium salt)

Read all of this leaflet carefully before you are given 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.
- 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 Sodium Injection is and what it is used for
2. What you need to know before Esomeprazole Sodium Injection is given to you
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1. What Esomeprazole Sodium Injection is and what it is used for

Esomeprazole Sodium Injection 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 Sodium Injection is used for the short-term treatment of certain conditions, when you are unable to have treatment by mouth. It 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.
- 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.

Children and adolescents aged 1-18 years

- '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.

2. What you need to know before Esomeprazole Sodium Injection is given to you

You must not be given Esomeprazole Sodium Injection
- 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 infection).

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.

Warning and Precautions
Talk to your doctor or nurse before you are given Esomeprazole Sodium Injection:
- 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 are given esomeprazole or after you are given 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).

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).

If you get 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.

This medicine may affect the way that your body absorbs vitamin B_{12}, 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 B_{12}:
- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

Other medicines and Esomeprazole Sodium Injection
Tell your doctor or nurse, 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.

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

Tell your doctor or nurse 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 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).
- 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).

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 you are given this medicine. Your doctor will decide whether you can take this medicine 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. However, side effects such as dizziness and blurred vision may uncommonly occur (see section 4). If affected, you should not drive or use machines.

Esomeprazole Sodium Injection contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium free".

3. How Esomeprazole Sodium Injection is given to you

Esomeprazole can be given to children and adolescents aged 1-18 years and adults, including the elderly.

Being given Esomeprazole Sodium Injection

Use in adults
- Esomeprazole will be given to you by your doctor who will decide how much you need.
- The recommended dose is 20 mg or 40 mg once a day.
- If you have severe liver problems, the maximum dose is 20 mg a day (GERD).
- 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.
- The recommended dose for prevention of rebleeding of gastric or duodenal ulcer is 80 mg administered as intravenous infusion 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.

Use in children and adolescents
- Esomeprazole 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 Sodium Injection than you should
If you think you have been given too much esomeprazole, talk to your doctor straight away.

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 and may affect up to 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.
- 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).
- 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 1000 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 10000 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 can not 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).
- 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 , pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance,
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esomeprazole Sodium Injection

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

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

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

Do not store above 25°C.
Keep the vial in outer carton, in order to protect from light. Vials can however, be stored exposed to normal indoor light outside the box for up to 24 hours.

Chemical and physical stability of reconstituted solution has been demonstrated for 12 hours at 25°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 and would normally not be longer than 12 hours at 2-8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice deterioration of drug product i.e melt back of cake and particulate matter in reconstituted solution.

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 Sodium Injection contains:
Esomeprazole Sodium Injection contains the active ingredient 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 further information on sodium content, see section 2.

What Esomeprazole Sodium Injection looks like and contents of the pack:
Esomeprazole Sodium Injection is white to off white, porous cake or powder. This is made into solution before it is given to you.

Esomeprazole Sodium Injection is available in 6 ml Ph.Eur type I clear glass vial closed with grey bromobutyl rubber stopper and purple aluminium flip-off seal.

Pack sizes:
1 x 1 vial
1 x 10 vials
1 x 50 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer:

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	**Name of the medicinal product**
Bulgaria	Esomeprazole Accord 40 mg Powder for solution for Injection/Infusion
Cyprus	Esomeprazole Accord 40 mg Powder for solution for Injection/Infusion
Denmark	Esomeprazole Accord 40 mg
Ireland	Esomeprazole 40 mg Powder for solution for Injection/Infusion
Iceland	Esomeprazol Accord 40 mg Stungulyfsstofn, lausn fyrir stungulyf / innrennslislyf
The Netherlands	Esomeprazol Accord 40 mg Poeder voor oplossing voor injectie / infusie
Norway	Esomeprazole Accord
Portugal	Esomeprazol Accord
Poland	Esomeprazol Accord
Sweden	Esomeprazole Accord 40 mg pulver till injektions-/infusionsvätska, lösning
United Kingdom (Northern Ireland)	Esomeprazole 40 mg Powder for solution for Injection/Infusion

The leaflet was last revised in 03/2024.

The following information is intended for healthcare professionals only

Esomeprazole Sodium Injection contains 40 mg of esomeprazole, as a sodium salt. Each vial also contains disodium edetate and sodium hydroxide (< 1 mmol sodium).

Vials are for single use only. If the entire reconstituted content of the vial is not required for a single dose, any unused solution should be discarded.

For further information on dose recommendations and storage conditions, see sections 3 and 5, respectively.

Preparation and Administration of Reconstituted Solution:
For the reconstitution of solution, withdraw the plastic cap of colour at the top of the vial of Esomeprazole Sodium Injection, 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 reconstituted solution for injection or infusion should be clear and colourless to very slightly yellow. It should be inspected visually for particulate matter and discolouration before administration and only clear solution should be used.

The shelf life after reconstitution in terms of chemical and physical stability has been demonstrated for 12 hours at 25°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 and would normally not be longer than 12 hours at 2-8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Esomeprazole Sodium 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% 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 section 3.

Esomeprazole Sodium 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% 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% sodium chloride for intravenous use.

For further information on dose administration, please see section 3.

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