

Package leaflet: information for the user

Esomeprazole NORMON 40 mg Powder for injectable solution and for infusion

esomeprazole

Please 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, nurse or pharmacist.
- 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 NORMON is and what it is used for
2. What you need to know before Esomeprazole NORMON is given to you
3. How Esomeprazole NORMON is given to you
4. Possible side effects
5. How to store Esomeprazole NORMON
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1. What Esomeprazole NORMON is and what it is used for

Esomeprazole NORMON 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 NORMON 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) 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 caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole NORMON 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 Esomeprazole NORMON is given to you You must not be given Esomeprazole NORMON 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 (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are taking a medicine containing nelfinavir (used to treat HIV).
- You must not be given Esomeprazole NORMON if any of the above applies to you.

If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Check with your doctor or nurse before you are given Esomeprazole NORMON if:

- You have severe liver problems.
- You have severe kidney problems.
- You have ever had a skin reaction after treatment with a medicine similar to Esomeprazole NORMON that reduces stomach acid.
- 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 NORMON. Remember to also mention any other ill-effects like pain in your joints.

Esomeprazole NORMON may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you are given Esomeprazole NORMON 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).

Other medicines and Esomeprazole NORMON

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This is because Esomeprazole NORMON can affect the way some medicines work and some medicines can have an effect on Esomeprazole NORMON.

You must not be given Esomeprazole NORMON 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 having Esomeprazole NORMON.
- 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 NORMON.
- 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 Esomeprazole NORMON treatment.
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

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 taking this medicine. Your doctor will decide whether you can be given Esomeprazole NORMON during this time.

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

Driving and using machines

Esomeprazole NORMON is not likely to affect you being able to drive or use any tools or machines.

Esomeprazole NORMON contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially "sodium-free"

3. How Esomeprazole NORMON is given to you

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

Being given Esomeprazole NORMON

Adults

- Esomeprazole NORMON 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 (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.
- The usual 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.

Children aged 1-18 years

- Esomeprazole NORMON will be given by your doctor who will decide how much you need.
- For children 1-11 years, the usual dose is 10 or 20 mg given once a day.
- For children 12-18 years, the usual 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 for up to 30 minutes.

If you are given too much Esomeprazole NORMON

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

4. Possible side effects

Like all medicines, Esomeprazole NORMON can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Esomeprazole NORMON 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.

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.

Rare (may affect up to 1 in 1,000 people)

- Blood problems such as a reduced number of white cells or platelets.
- 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.

Unknown frequency (the frequency cannot be estimated from the available data)

- Inflammation in the intestine (may cause diarrhea)
 - Rash, possibly with pain in the joints
- If you are taking esomeprazole NORMON for more than three months, your magnesium levels may decrease. Low magnesium levels may cause fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness and an increase in heart rate. If you have any of these symptoms, see your physician immediately. Low magnesium levels may also

cause a decrease in potassium and calcium levels. Your physician may decide to do periodic blood tests in order to monitor your magnesium levels.

- If you are taking proton pump inhibitors such as esomeprazole NORMON, especially for more than a year, it may slightly increase the risk of hip, wrist and spinal fracture. Notify your physician if you have osteoporosis or if you are taking corticosteroids (it may increase the risk of osteoporosis).

In rare cases, esomeprazole NORMON may affect white blood cells, causing an immune deficiency. If you have an infection with symptoms such as fever with **severe** worsening of your general health or fever with symptoms of a local infection such as pain in the neck, throat, mouth or difficulty urinating, you should consult your physician as soon as possible in order to rule out a decrease in white blood cell counts (agranulocytosis) through a blood test. In this case, it is important that you report your medication.

Do not be alarmed by this list of possible adverse effects. It is likely that you will not have any of them. If you experience side effects, speak with your physician or pharmacist even if they are not on this leaflet.

5. How to store Esomeprazole NORMON

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

This medicine should be kept in a safe place where children cannot see or reach it.

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.

Do not store above 30°C. Protect from humidity.

Keep the vial in the 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.

Medicinal products should not be poured down the drain or thrown into the rubbish. Ask your pharmacist how to dispose of medicinal products you do not need. This will help to protect the environment.

6. Contents of the pack and other information What Esomeprazole NORMON contains

The active substance is esomeprazole sodium. Each vial of powder for injectable solution and for 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 NORMON looks like and contents of the pack

Esomeprazole NORMON is a white to off-white porous powder. This is made into a solution before it is given to you.

Pack sizes: 1 vial and 50 vials presented in glass vial closed with a stopper and sealed with a capsule in packs containing.

Not all the pack sizes are marketed in all the countries.

Marketing Authorisation Holder and Manufacturer

Laboratorios NORMON, S.A.

Ronda de Valdecarrizo, 6

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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

Esomeprazole NORMON contains 40 mg of esomeprazole, such as sodium salt. Each vial also contains disodium edetate and sodium hydroxide (<1 mmol sodium). Vials are for single use only. Failure to use the entire contents of the reconstituted vial for a single dose should be discarded unused solution. For more information on the dosage recommendations and storage conditions, see sections 3 and 5, respectively.

Method of preparation of reconstituted solution

For reconstitution of the solution, remove the plastic lid colored upper Esomeprazole NORMON vial and pierce the stopper at the center of the circle marked maintaining the needle in an upright position in order to properly traverse the plug. The reconstituted solution for injection or infusion should be clear and colorless to slightly yellow. Should be inspected visually for particulate matter and discoloration prior to administration and should be used only clear solution. It has been shown useful life after reconstitution in terms of physical and chemical stability for 12 hours at 30 ° C. However, from a microbiological viewpoint, use the product immediately.

Injection of Esomeprazole NORMON

To prepare a solution for injection:

Injection 40 mg

A solution for injection (8 mg/ml) is prepared by adding 5 mL of 0.9% sodium chloride for intravenous use to the 40 mg vial with esomeprazole.

The reconstituted solution should be given as an intravenous injection over a period of at least 3 minutes.

For more information on the administration of the dose, please see the data sheet, section 4.2.

Infusion of Esomeprazole NORMON

To prepare a solution for infusion:

Infusion 40 mg

A solution for infusion is prepared by dissolving the content of one vial with esomeprazole in up to 100 mL 0.9% sodium chloride for intravenous use.

Infusion 80 mg

A solution for infusion is prepared by dissolving the content of two vials of esomeprazole 40 mg in up to 100 ml of 0.9% sodium chloride for intravenous use.

For more information on the administration of the dose, please see the data sheet, section 4.2.