Esomeprazole AN

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given Esomeprazole AN?

Esomeprazole AN contains the active ingredient esomeprazole sodium. Esomeprazole AN is used to treat Reflux Oesophagitis, Bleeding Peptic Ulcers and Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy. Esomeprazole AN will only be used if you are unable to take tablets.

For more information, see Section 1. Why am I being given Esomeprazole AN? in the full CMI.

2. What should I know before I am given Esomeprazole AN?

Do not use if you have ever had an allergic reaction to Esomeprazole AN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given Esomeprazole AN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Esomeprazole AN and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given Esomeprazole AN?

- Esomeprazole AN can be either injected into a vein over a period of at least 3 minutes for adults or injected slowly over a period of 10 to 30 minutes in either adults or children. It must only be given by a nurse or doctor.
- The dosage and the period of time over which it is given will depend on your condition. Your doctor will have had experience injecting Esomeprazole AN and will choose the best dose for you.

More instructions can be found in Section 4. How will I be given Esomeprazole AN? in the full CMI.

5. What should I know while using Esomeprazole AN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Esomeprazole AN. • Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Esomeprazole AN
Things you should not do	• Do not stop using this Esomeprazole AN suddenly, unless you have discussed this with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Esomeprazole AN affects you.
Looking after your medicine	• Esomeprazole AN will be stored by your doctor or pharmacist under the recommended conditions.

For more information, see Section 5. What should I know while using Esomeprazole AN? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include constipation, nausea or vomiting, diarrhoea, headache, wind, stomach pain, skin rash, itchy skin, injection site reaction such as redness, discomfort or swelling, dizziness and dry mouth.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Esomeprazole AN

Active ingredient: esomeprazole sodium

Consumer Medicine Information (CMI)

This leaflet provides important information about using Esomeprazole AN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Esomeprazole AN.**

Where to find information in this leaflet:

1. Why am I being given Esomeprazole AN?
2. What should I know before I am given Esomeprazole AN?
3. What if I am taking other medicines?
4. How will I be given Esomeprazole AN?
5. What should I know while using Esomeprazole AN?
6. Are there any side effects?
7. Product details

1. Why am I being given Esomeprazole AN?

Esomeprazole AN contains the active ingredient esomeprazole sodium. Esomeprazole AN belongs to a group of medicines called "proton pump inhibitors". These work by reducing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place.

Esomeprazole AN will only be used if you are unable to take tablets.

Reflux Oesophagitis

Esomeprazole AN is used to treat reflux oesophagitis or reflux disease in the short-term. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus). Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Bleeding Peptic Ulcers

Peptic ulcers are ulcers in the stomach or duodenum (tube leading out from the stomach). When these ulcers become severe enough, they start to bleed. Esomeprazole AN can be injected into your veins to treat these bleeding ulcers. Treatment with Esomeprazole AN should be followed with other therapy to reduce the amount of acid made by the stomach. This is to help your ulcer/s to heal.

Upper gastrointestinal symptoms associated with non-steroidal anti- inflammatory drugs (NSAIDs) therapy

If you are unable to eat or drink, Esomeprazole AN may be given to treat the symptoms of pain or discomfort in the stomach caused by NSAIDs (medicines used to treat pain or inflammation). Esomeprazole AN may also be used to help and prevent ulcers caused by NSAIDs.

2. What should I know before I am given Esomeprazole AN?

Warnings

Do not use Esomeprazole AN if:

- You have allergies to esomeprazole sodium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have allergies to any medicines containing a proton-pump inhibitor.

Some of the symptoms of an allergic reaction may include:

- skin rash
- difficulty in breathing
- hay fever
- feeling faint

Do not use Esomeprazole AN if you are taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by Esomeprazole AN.

Check with your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any other medical conditions; e.g. liver disease
- been diagnosed with osteoporosis
- ever had a skin reaction after treatment with a medicine similar to Esomeprazole AN that reduces stomach acid

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not use Esomeprazole if you are pregnant or breastfeeding unless your doctor says so. **Ask your doctor about the risks and benefits involved**.

It is not known if it is safe for you to be given Esomeprazole AN while you are pregnant. It may affect your baby.

It is not known if your baby can take in Esomeprazole AN from breast milk if you are breastfeeding.

Children younger than 1 year

Esomeprazole AN is not approved for use in children less than 1 year of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not use Esomeprazole AN if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat Human Immunodeficiency Virus (HIV)
- cilostazol - a medicine used to treat intermittent claudication

Some medicines may interfere with Esomeprazole AN and affect how it works. These include:

- phenytoin - a medicine used to treat epilepsy
- warfarin and clopidogrel - medicines used to prevent blood clots
- diazepam - a medicine used to treat anxiety and some other conditions
- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin, erythromycin and rifampicin - medicines used to treat bacterial infections
- digoxin - a medicine used to treat heart conditions
- methotrexate - a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by Esomeprazole or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor can tell you what to do if you are taking any other medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are being given Esomeprazole AN.

If you have not told your doctor about any of these things, tell them before you are given Esomeprazole AN.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Esomeprazole AN.

4. How will I be given Esomeprazole AN?

How you are given Esomeprazole AN

Esomeprazole AN can be either injected into a vein over a period of at least 3 minutes for adults or injected slowly over a period of 10 to 30 minutes in either adults or children. This is called an intravenous infusion. In adults, Esomeprazole AN can be infused slowly over a longer period of 3 days.

The dosage and the period of time over which it is given will depend on your condition.

Your doctor will have had experience injecting Esomeprazole AN and will choose the best dose for you. They will be willing to discuss this decision with you.

In most patients, Esomeprazole AN relieves symptoms rapidly and it will be replaced with oral treatment as soon as you are well enough to swallow.

If you miss an appointment to get Esomeprazole AN

- Call your doctor right away to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine. If you stop receiving Esomeprazole AN.
- Do not stop treatment with Esomeprazole AN unless you have discussed this with your doctor.
- If you have any further questions about your treatment, ask your doctor.

If you are given too much Esomeprazole AN

The doctor or nurse giving you Esomeprazole AN will be experienced in the use of Esomeprazole AN, so it is unlikely that you will be given an overdose. However, if you do think that you have been given too much Esomeprazole AN you should speak to your doctor immediately.

5. What should I know while using Esomeprazole AN?

Things you should do

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Esomeprazole AN.

Call your doctor straight away if you:

- have a serious allergic reaction to Esomeprazole AN. Symptoms may include swelling of your face, lips, tongue or other parts of the body, wheezing or difficulty breathing.

Remind any doctor, dentist or pharmacist you visit that you are using Esomeprazole AN.

Things you should not do

- Do not stop using Esomeprazole AN suddenly, unless you have discussed this with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Esomeprazole AN affects you.

Looking after your medicine

- Esomeprazole AN will be stored by your doctor or pharmacist under the recommended conditions.
- It should be kept in a cool, dry place, out of the reach of children where the temperature stays below 25°C.

Esomeprazole AN will only be used if the solution is clear, the package in undamaged and the use by (expiry) date marked on the pack has not been passed.

Getting rid of any unwanted medicine

Any Esomeprazole AN which is not used will be disposed of in a safe manner by your doctor or pharmacist.

Esomeprazole AN contains no antimicrobial agent. Each Esomeprazole AN vial is for single use in one patient only. Any remaining contents should be discarded.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• constipation • nausea or vomiting • diarrhoea • headache • wind • stomach pain • skin rash, itchy skin • injection site reaction such as redness, discomfort or swelling • dizziness • dry mouth	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• muscle pain or weakness, joint pain • "pins and needles" • changes in sleep patterns • fever • mood changes, confusion or depression • increase in breast size (males) • increased bruising • increased sweating • hair loss • changes in vision • tremor • yellowing of the eyes and skin • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin. This may be associated with a high fever and joint pains • blood in the urine • increased or decreased urine output • skin reaction, especially in sun exposed areas, with joint pain • muscle twitching or jerking movements • irregular (fast or slow) heartbeat • loss of consciousness or awareness	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Occasionally, Esomeprazole AN may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Esomeprazole AN contains

Active ingredient (main ingredient)	Esomeprazole sodium
Other ingredients (inactive ingredients)	• Disodium edetate • Sodium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

What Esomeprazole AN looks like

Esomeprazole AN is a white or almost white powder in a glass vial. This powder must be mixed with normal saline before injection or infusion.

Esomeprazole AN is supplied as:

Esomeprazole AN 40 mg powder for injection.

AUST R 203825

Who distributes Esomeprazole AN

Juno Pharmaceuticals Pty Ltd

15-17 Chapel Street,

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www.junopharm.com.au

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