

ESOMEPRAZOLE AN

Esomeprazole sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Esomeprazole AN. It does not contain all the information that is known about Esomeprazole AN.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of your being given Esomeprazole AN against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What ESOMEPRAZOLE AN is used for

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.

How ESOMEPRAZOLE AN works

Esomeprazole AN is a type of medicine called a proton-pump inhibitor.

Esomeprazole AN works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Your doctor will have explained why you are being treated with Esomeprazole AN and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use.

Ask your doctor if you want more information.

There is no evidence that Esomeprazole AN is addictive.

Before you are given ESOMEPRAZOLE AN

When you must not have it

Do not use Esomeprazole AN if you have allergies to:

- **Esomeprazole AN or any ingredient listed at the end of this leaflet**
- **Any medicines containing a proton-pump inhibitor.**

Symptoms of an allergic reaction include skin rash, difficulty in breathing, hayfever or 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.

Esomeprazole AN is not recommended for use in children.

There is no specific information about use in children, so Esomeprazole AN is not recommended in children.

Esomeprazole AN will only be used if the solution is clear, the package is undamaged and the

use by (expiry) date marked on the pack has not been passed.

Before you are given it

You must tell your doctor if:

- 1. you have any allergies to any other medicines, foods, dyes or preservatives.**
- 2. you have any other medical conditions e.g. liver disease.**

Do not use Esomeprazole AN 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 .

Taking other medicines

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

- atazanavir, a medicine used to treat Human Immunodeficiency Virus (HIV).
- cilostazol, a medicine used to treat intermittent claudication

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

Some medicines and Esomeprazole AN may interfere with each other. These include:

- phenytoin, a medicine used to treat epilepsy
- warfarin, a medicine used to prevent blood clots
- diazepam, a medicine used to treat anxiety and some other conditions
- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- cisapride

- medicines used to treat depression such as citalopram, clomipramine and imipramine
- St John's wort, a herbal remedy used to treat mood disorders
- medicines used to treat bacterial infections such as clarithromycin erythromycin and rifampicin
- medicines for HIV treatment such as nelfinavir
- digoxin, a medicine used to treat heart problems
- methotrexate, a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer.

These medicines may be affected by Esomeprazole AN 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.

How ESOMEPRAZOLE AN is given

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

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.

Overdose

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.

Side effects

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

Esomeprazole AN helps most people with stomach or duodenal ulcers or reflux disease, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- 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.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- increase in breast size (males)
- fever
- 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
- blood in the urine.

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 if you notice anything else that is making you feel unwell.

Some people may get other side effects while being given Esomeprazole AN.

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

Product description

Esomeprazole AN powder for injection contains esomeprazole sodium 42.50 mg (this is equal to 40 mg esomeprazole) as the active ingredient; plus, disodium edetate and sodium hydroxide.

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

Sponsor

Amneal Pharma Australia Pty Ltd
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South Yarra VIC 3141

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After being given it

Storage

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.

Disposal

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