

NEXIUM[®] INTRAVENOUS

esomeprazole sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about NEXIUM Intravenous (IV). It does not contain all the information that is known about NEXIUM IV.

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 NEXIUM IV 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 NEXIUM IV is used for

NEXIUM IV will only be used if you are unable to take tablets.

Reflux Oesophagitis

NEXIUM IV 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. In adults, NEXIUM IV can be injected into your veins to treat these bleeding ulcers. Treatment with NEXIUM IV 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

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

How NEXIUM IV works

NEXIUM IV is a type of medicine called a proton-pump inhibitor.

NEXIUM IV 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 NEXIUM

IV 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 NEXIUM IV is addictive.

Before you are given NEXIUM IV

When you must not have it

Do not use NEXIUM IV if you have allergies to:

- **NEXIUM IV 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 NEXIUM IV 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 NEXIUM IV.

NEXIUM IV is not approved for use in children less than 1 year of age.

NEXIUM IV 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 you have:

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

Do not use NEXIUM IV 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 NEXIUM IV while you are pregnant. It may affect your baby.

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

Taking other medicines

Do not use NEXIUM IV 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

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 NEXIUM IV may interfere with each other. 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 problems
- 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 NEXIUM IV 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 NEXIUM IV.

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

How NEXIUM IV is given

NEXIUM IV 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, NEXIUM IV 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 NEXIUM IV and will choose the best dose for you. They will be willing to discuss this decision with you.

In most patients, NEXIUM IV 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 NEXIUM IV will be experienced in the use of NEXIUM IV, 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 NEXIUM IV.

NEXIUM IV 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
- skin reaction, especially in sun-exposed areas, with joint pain

Occasionally, NEXIUM IV 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 NEXIUM IV.

After being given it

Storage

NEXIUM IV 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 NEXIUM IV which is not used will be disposed of in a safe manner by your doctor or pharmacist.

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

Product description

NEXIUM IV contains esomeprazole sodium 42.6 mg (this is equal to 40 mg esomeprazole) as the active ingredient; plus disodium edetate and sodium hydroxide.

This powder has to be mixed with normal saline before injection or infusion.

Sponsor

AstraZeneca Pty Ltd
 ABN 54 009 682 311
 66 Talavera Road
 Macquarie Park NSW 2113

Telephone: 1800 805 342

Australian Registration Number:
 NEXIUM IV - 96678

This leaflet was prepared in February 2019.

NEXIUM® is a registered trade mark of the AstraZeneca group of companies.

© AstraZeneca 2019

Doc ID-002262356 V7.0