

FINAL PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

NEXIAM 40 mg IV (Powder for solution for injection and infusion)

Read this entire leaflet carefully before are given NEXIAM IV

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: **S4**

PROPRIETARY NAME (and dosage form):

Nexiam® 40 mg IV (Powder for solution for injection and infusion)

The active substance is esomeprazole

1. WHAT NEXIAM 40 mg IV CONTAINS:

The active substance is esomeprazole sodium 42,5 mg, equivalent to esomeprazole 40 mg.

The other ingredients are disodium edetate dihydrate and sodium hydroxide.

2. WHAT NEXIAM 40 mg IV IS USED FOR:

NEXIAM is a type of medicine called a 'proton pump inhibitor'. It reduces the production of acid in your stomach.

NEXIAM 40 mg IV is approved for treating the following conditions:

- Inflammation (swelling) and pain in the food pipe caused by a return flow of fluid from the stomach (erosive reflux oesophagitis)
- Disease with symptoms e.g. heartburn and regurgitation, caused by a return flow of fluid from the stomach (treatment of severe symptoms of reflux disease)
- Short term maintenance of haemostasis and prevention of rebleeding in patients following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

3. BEFORE YOU ARE GIVEN NEXIAM 40 mg IV:

Do not receive NEXIAM 40 mg IV:

You will not be given NEXIAM 40 mg IV if you are allergic to esomeprazole, substituted benzimidazoles or any other ingredients of NEXIAM.

Take special care with NEXIAM 40 mg IV:

While you are receiving NEXIAM tell your doctor, pharmacist or other health care professional:

if you notice any of the following:

- Pain or indigestion occurring during treatment with NEXIAM 40 mg IV.
- you begin to vomit blood or food
- you pass black (blood stained) stools. You should contact your doctor immediately.
- if you are taking the following medicines: medicines used to prevent fungal infections (itraconazole, ketoconazole, voriconazole), anxiousness (diazepam), fitting (phenytoin),

blood clotting (warfarin), intermittent claudication (cilostazol) and medicines used to speed up stomach emptying (cisapride).

- if you have severe liver problems. You should discuss this with your doctor, as he/she may wish to reduce the dose.
- if you have severe kidney problems. You should discuss this with your doctor.
- NEXIAM 40 mg IV should not be used in children.

Pregnancy and breast feeding:

Before being given NEXIAM 40 mg IV, tell your doctor if you are pregnant or breast feeding.

You should only be given NEXIAM on the advice of your doctor.

If you are pregnant or breast feeding your baby while being given NEXIAM, please consult your doctor, pharmacist or healthcare professional for advice.

Driving and using machinery:

NEXIAM 40 mg IV is unlikely to affect your ability to drive or to operate machinery.

Important information about some of the ingredients of NEXIAM 40 mg IV:

Taking other medicines with NEXIAM:

You should always inform doctor about all medicines you use, including those you have bought without a prescription.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of NEXIAM 40 mg IV with these medicines may cause undesirable

interactions. Please consult your doctor, pharmacist or other health care professional for advice.

The other medicine's effects may be influenced if NEXIAM 40 mg IV is used at the same time as some medicines used to prevent fungal infections (itraconazole, ketoconazole, voriconazole), anxiousness (diazepam), fitting (phenytoin), blood clotting (warfarin), intermittent claudication (cilostazol) and medicines used to speed up stomach emptying (cisapride).

Using NEXIAM at the same time as some drugs for HIV, such as atazanavir and nelfinavir is not recommended.

4. HOW NEXIAM 40 mg IV IS USED:

A doctor/nurse will give you NEXIAM 40 mg IV as an injection or infusion for up to 7 days if you are not able to take a tablet. As soon as you can take oral medication again you will continue to take NEXIAM as tablets. The dose given is decided by the doctor.

Erosive reflux oesophagitis:

The usual dose for treatment of inflammation (swelling) and pain in the food pipe is NEXIAM 40 mg once a day. Total treatment time is 4 to 8 weeks depending on the severity of the disease and how you respond to treatment.

To stop the disease coming back and treatment of severe symptoms of reflux disease:

The usual dose for treatment of symptoms, e.g. heartburn and regurgitation is NEXIAM 20 mg once daily. If the symptoms have not disappeared after 4 weeks you should talk to your doctor.

The usual dose for maintenance of haemostasis and prevention of rebleeding of gastric or duodenal ulcers is 80 mg administered as intravenous infusion over 30 minutes followed by a continuous infusion of 8 mg/hour given over 3 days.

The intravenous treatment period should be followed by acid suppression therapy with NEXIAM 40 mg orally once daily for 4 weeks.

NEXIAM 40 mg IV can be used in the elderly.

Do not share medicines prescribed for you with any other person.

If you have been given more NEXIAM 40 mg IV than you should:

If you suspect that you have been given too much NEXIAM 40 mg IV, you may experience some of the possible side effects listed below, please inform your doctor.

5. POSSIBLE SIDE EFFECTS:

NEXIAM can have side effects.

Not all side effects reported for NEXIAM are included in this leaflet. Should your general health worsen while receiving NEXIAM, please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor if you notice any of the following:

Common side effects:

Headache, dizziness, stomach pain, diarrhoea, wind, nausea and vomiting, constipation, dry mouth, skin reactions (injection site reaction)

Uncommon side effects:

Skin reactions (rash, dermatitis, itching, hives), sensation of burning/prickling/numbness, difficulty sleeping, feeling sleepy, dizziness, vertigo, peripheral swelling.

Rare side effects:

Blurred vision, severe allergic reactions (swelling, anaphylactic reaction/shock), muscular pain, blood disorders (reduced number of cells in the blood i.e. leukopenia and thrombocytopenia), depression, low blood sodium, nervousness, confusion, taste disorders, tightness in the chest, inflammation in the mouth, gastrointestinal fungal infection, inflammation of the liver (with or without jaundice), hair loss, sensitivity to sunlight, sore joints, feeling ill and increased sweating may occur.

Very rare side effects:

Severe skin disorders, other blood disorders (decrease in red and white blood cells), aggression, hallucination, impaired liver function, decreased consciousness, muscular weakness, inflammation of the kidney and development of breasts in males have been reported during treatment with NEXIAM

The following side effect may also occur with NEXIAM. This would only be seen when a blood test is taken: increase in the amount of liver enzymes.

6. STORING AND DISPOSING OF NEXIAM 40 mg IV:

NEXIAM 40 mg IV should be stored at or below 25 °C in the outer container which it is provided in, since this protects the vial from light.

Your doctor or the hospital will store NEXIAM 40 mg IV for injection and infusion. The staff are responsible for the storing, dispensing and disposing of NEXIAM 40 mg IV in the correct way.

Keep all medicines out of reach of children.

7. PRESENTATION OF NEXIAM 40 mg IV:

Colourless glass vials with a rubber stopper, cap made of aluminium and a plastic flip off seal.

Pack sizes: 10 vials.

8. IDENTIFICATION OF NEXIAM 40 mg IV:

A white to off white porous cake or powder in a 5 ml vial.

9. REGISTRATION NUMBER:

A38/11.4.3/0384

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West,

Bryanston, Johannesburg

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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