PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NEXIAM® 40 mg IV, 40 mg powder for solution for injection and infusion

Esomeprazole

Read all of this leaflet carefully before you are given NEXIAM 40 mg IV

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NEXIAM 40 mg IV 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.

What is in this leaflet

1. What NEXIAM 40 mg IV is and what it is used for
2. What you need to know before you take NEXIAM 40 mg IV
3. How to take NEXIAM 40 mg IV
4. Possible side effects
5. How to store NEXIAM 40 mg IV
6. Contents of the pack and other information

1. What NEXIAM 40 mg IV is and what it is used for

NEXIAM 40 mg IV is a type of medicine called a “proton pump inhibitor” (medicines used to treat gastric ulcers [open sores that develop on the lining of the stomach]). 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 acidic fluid from the stomach (erosive reflux oesophagitis).

- Disease with symptoms e.g. heartburn and regurgitation, caused by a return flow of acidic fluid from the stomach (treatment of severe symptoms of reflux disease).

Short term maintenance of haemostasis (stopping of bleeding) and prevention of rebleeding in patients following a procedure called therapeutic endoscopy, during which treatment for acute bleeding gastric or duodenal ulcers is carried out.

2. What you need to know before you are given NEXIAM 40 mg IV

NEXIAM 40 mg IV should not be administered to you:

- if you are hypersensitive (allergic) to esomeprazole, substituted benzimidazoles or any of the other ingredients of NEXIAM 40 mg IV (listed in section 6).
- if you are taking medicine for HIV treatment (atazanavir or nelfinavir).

Warnings and precautions

Take special care with NEXIAM 40 mg IV:

While you are receiving NEXIAM 40 mg IV, 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.
- if you have severe, debilitating diarrhoea (known as Clostridium Difficile- associated diarrhoea, *Salmonella* or *Campylobacter*), that does not improve. Symptoms may include watery stools, stomach pain and fever.
- if you experience any severe, painful, blistering or peeling skin rash (known as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms). You should stop using NEXIAM 40 mg IV and contact your doctor immediately.
- if you experience low levels of magnesium in your body. Symptoms include tiredness, muscles spasms, disorientation, convulsions (fits), dizziness and an abnormal heartbeat. Your doctor may conduct regular blood tests to monitor your magnesium levels.

NEXIAM 40 mg IV should not be used in children.

Proton pump inhibitors (like NEXIAM 40 mg IV) may be associated with a small increased risk for osteoporotic bone fractures (osteoporosis is a condition where certain bones become brittle).

Please inform your doctor if you have been diagnosed with osteoporosis (brittle bone disease).

Other medicines and NEXIAM 40 mg IV

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

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

Inform your doctor if you are taking any of the following medicines to treat or prevent:

- fungal infections (itraconazole, ketoconazole, voriconazole)

- anxiousness (diazepam)
- fitting (phenytoin and sodium valproate)
- blood clotting (warfarin and clopidogrel)

intermittent claudication, a condition where leg pain is caused by poor circulation (cilostazol)

- transplant rejection (tacrolimus)
- medicines used to speed up stomach emptying (cisapride)
- if you are using certain type of anti-cancer medicines (such as erlotinib or another medicine from the same class)
- taking NEXIAM 40 mg IV at the same time as some medicines for HIV, such as saquinavir and tipranavir
- heart problems (digoxin)
- cancer or rheumatoid arthritis (e.g. methotrexate)
- treatment for tuberculosis (rifampicin)
- depression (St John's wort (*Hypericum perforatum*)).

Using NEXIAM 40 mg IV at the same time as protease inhibitors (medicines for HIV infection), e.g. indinavir, atazanavir and nelfinavir, is not recommended, as NEXIAM 40 mg IV may reduce the blood levels of protease inhibitors.

NEXIAM 40 mg IV may affect the way that your body absorbs vitamin B12, particularly if you need to take it for a long time.

NEXIAM 40 mg IV may interfere with laboratory tests to investigate neuroendocrine tumours. Your doctor will instruct you to stop taking NEXIAM 40 mg IV 5 days before the tests are done.

Pregnancy and breastfeeding

You should not receive NEXIAM 40 mg IV if you are pregnant or breastfeeding your baby as safety has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking

NEXIAM 40 mg IV.

Driving and using machines

NEXIAM 40 mg IV may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery.

NEXIAM contains sodium

NEXIAM 40 mg IV contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How NEXIAM 40 mg IV will be administered

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

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 40 mg IV as tablets. The dose given is decided by the doctor.

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

Since a health care provider will administer NEXIAM 40 mg IV, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdose.

If you have missed a dose of NEXIAM 40 mg IV

As NEXIAM 40 mg IV will be administered under the supervision of your doctor, it is unlikely that you will miss a dose. However, if you have any concerns about the dose you receive, please tell your doctor.

4. Possible side effects

NEXIAM 40 mg IV can have side effects.

Not all side effects reported for NEXIAM 40 mg IV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving NEXIAM 40 mg IV, please consult your health care provider for advice.

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

- 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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NEXIAM 40 mg IV. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- diarrhoea
- wind
- stomach pain
- nausea and vomiting (feeling sick/being sick)
- constipation
- skin reactions (injection site reaction)

Less frequent side effects:

- skin reactions (rash, dermatitis, itching, hives [itchy bumps])
- sensation of burning/prickling/numbness
- difficulty sleeping
- feeling sleepy

- dizziness
- vertigo
- dry mouth
- peripheral swelling
- blurred (decreased clarity) vision
- muscular pain
- blood disorders (reduced number of cells in 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
- gastrointestinal infections
- inflammation of the liver (with or without jaundice)
- hair loss
- sensitivity to sunlight
- sore joints
- feeling ill and increased sweating may occur
- other blood disorders (decrease in red and white blood cells)
- aggression
- hallucination
- impaired liver function
- decreased consciousness
- muscular weakness
- inflammation of the kidney

- development of breasts in males
- low blood magnesium (which may result in low blood calcium and/or low blood potassium)
- inflammation of the gut
- fracture of your hip, wrist or spine.

The following side effect may also occur with NEXIAM 40 mg IV. This would only be seen when a blood test is taken: increase in the amount of liver enzymes.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NEXIAM 40 mg IV.

5. How to store NEXIAM 40 mg IV

Store all medicines out of reach of children.

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.

6. Contents of the pack and other information

What NEXIAM 40 mg IV contains

The active substance is esomeprazole 40 mg as esomeprazole sodium.

The other ingredients are disodium edetate dihydrate and sodium hydroxide.

What NEXIAM 40 mg IV looks like and contents of the pack

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

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

Pack sizes: 1 or 10 vials.

Holder of certificate of registration

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Access to corresponding Professional Information

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