PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NEXIAM® 20 mg: 20 mg gastric resistant tablet

NEXIAM® 40 mg: 40 mg gastric resistant tablet

Esomeprazole magnesium trihydrate

Contains sugar: sucrose

NEXIAM 20 mg: 28 mg sugar spheres per tablet

NEXIAM 40 mg: 30 mg sugar spheres per tablet

Read all of this leaflet carefully before you start taking NEXIAM

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

1. What NEXIAM is and what it is used for

NEXIAM 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 is used 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 (symptomatic treatment of gastro-oesophageal reflux disease - GORD) and the prevention of this condition from happening again.
- Prevention of ulcers caused by a medicine used for pain and inflammation.
- Infection with bacteria called *Helicobacter pylori* that cause ulcers in the stomach in combination with appropriate antibiotics.
- A hypersecretory condition which causes excess secretion of acid in the stomach known as Zollinger-Ellison Syndrome.

2. What you need to know before you take NEXIAM

Do not take NEXIAM

- If you are hypersensitive (allergic) to esomeprazole or any of the other ingredients of NEXIAM (listed in section 6).
- If you are allergic to other “proton pump inhibitors”.
- If you are taking medicine for HIV treatment (atazanavir or nelfinavir).

Warnings and precautions

Take special care with NEXIAM:

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

- if you notice any of the following:
  - if you feel that you are losing weight without trying to lose it.
  - you begin to vomit blood or food.
  - you pass black (blood-stained) stools. You should contact your doctor immediately.
- if you are taking any of the following medicines: medicines used to prevent fungal infections (itraconazole, ketoconazole, voriconazole), anxiety medicine (diazepam), medicines used to

prevent fitting (phenytoin), medicines used to prevent blood clotting (warfarin, clopidogrel), intermittent claudication (cilostazol), medicines used to speed up stomach emptying (cisapride) and if you are using a certain type of antimalignancy medicine (such as erlotinib or another antimalignancy medicine from the same class).

- 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 taking NEXIAM 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.

Proton pump inhibitors (like NEXIAM) 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

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

- The medicine's effects may be influenced if NEXIAM is taken at the same time as some medicines used to prevent fungal infections (itraconazole, ketoconazole voriconazole), anxiety medicine (diazepam), medicines used to prevent fitting (phenytoin), medicines used to prevent

blood clotting (warfarin or clopidogrel), intermittent claudication [muscle pain that happens in your legs when you are active and then stops when you rest] (cilostazol), transplant rejection (tacrolimus), medicines used to speed up stomach emptying (cisapride), heart problems (digoxin), and also if you are using treatment for tuberculosis (rifampicin), St. John's wort (*Hypericum perforatum*) (used to treat depression), or certain type of antimalignancy medicines (such as erlotinib or another antimalignancy medicine from the same class).

- NEXIAM should not be taken at the same time as protease inhibitors (medicines for HIV infection), e.g. indinavir, atazanavir and nelfinavir, as NEXIAM may reduce the blood levels of protease inhibitors.
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer), NEXIAM may need to be temporarily withdrawn.
- NEXIAM may affect the way that your body absorbs vitamin B12, particularly if you need to take it for a long time.
- NEXIAM may interfere with laboratory tests to investigate neuroendocrine tumours. Your doctor will instruct you to stop taking NEXIAM 5 days before the tests are done.

Pregnancy and breastfeeding

You should not take NEXIAM if you are pregnant or breastfeeding your baby.

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.

Driving and using machines

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

NEXIAM contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before giving NEXIAM.

NEXIAM contains sodium

NEXIAM 20 mg and NEXIAM 40 mg contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take NEXIAM

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

Always take NEXIAM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The tablets should not be chewed or crushed. They should be swallowed whole, with liquid.

The tablets can also be dispersed in half a glass of non-carbonated water where it will break apart, making it easier to swallow. Do not use any other liquids. Stir until the tablet/s disintegrate and be sure to swallow all the tiny pellets that come out of the tablet without chewing them. Do not let the pellets sit in the water for more than 30 minutes before drinking. After drinking, rinse the glass with water and drink this as well.

Your doctor will prescribe the correct dose and duration of treatment for your condition.

NEXIAM can be used in the elderly.

Try to take your medicine at the same time each day.

If you have the impression that the effect of NEXIAM is too strong or too weak, talk to your doctor or pharmacist.

If you take more NEXIAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, the nearest hospital or poison centre.

If you forget to take NEXIAM

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, and just take the next dose on time. Do not take a double dose to make up for forgotten individual doses.

4. 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 or if you experience any untoward effects while taking NEXIAM, please consult your health care provider for advice.

If any of the following happens, stop taking NEXIAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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 (small pocket of fluid in the upper skin layers) or peeling (loss of the upper layer of your skin). 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. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- stomach pain
- diarrhoea
- wind
- feeling sick/being sick
- constipation

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 and peripheral swelling
- blurred (decreased clarity) vision
- severe allergic reactions (swelling, anaphylactic reaction/shock)
- 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 infection
- inflammation of the liver (with or without jaundice)
- hair loss
- sensitivity to sunlight
- sore joints
- feeling ill and increased sweating may occur
- severe skin disorders
- other blood disorders (agranulocytosis and pancytopenia)

- 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 in the gut (leading to diarrhoea)
- fracture of your hip, wrist or spine.

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.

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 (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NEXIAM.

5. How to store NEXIAM

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in a dry place. Keep the container tightly closed (bottle).

Do not use NEXIAM after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NEXIAM contains

The active substance is esomeprazole.

NEXIAM 20 mg:

Each gastric-resistant tablet contains esomeprazole magnesium trihydrate 22,3 mg (equivalent to esomeprazole 20 mg) in the form of a multiple unit pellet system (MUPS).

NEXIAM 40 mg:

Each gastric-resistant tablet contains esomeprazole magnesium trihydrate 44,5 mg (equivalent to esomeprazole 40 mg) in the form of a multiple unit pellet system (MUPS).

The other ingredients in NEXIAM 20 mg and 40 mg tablets are:

Crospovidone, glycerol monostearate, hypromellose, hydroxypropylcellulose, iron oxide, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, microcrystalline cellulose, macrogol, polysorbate 80, synthetic paraffin, sugar spheres (sucrose and maize starch), sodium stearyl fumarate, talc, triethyl citrate, titanium dioxide.

What NEXIAM looks like and contents of the pack

NEXIAM 20 mg tablet is a light pink, oblong, biconvex, film-coated tablet engraved “20 mg” on one side and A/EH on the other side.

NEXIAM 40 mg tablet is a pink, oblong, biconvex, film-coated tablet engraved “40 mg” on one side and A/EI on the other side.

White HDPE bottles (with desiccated caps) of 2, 5, 7, 14, 15, 28, 30, 56, 60 or 100 tablets.

PVC/aluminium blister packages of 3, 7, 14, 15, 28, 30, 50, 56, 60, 98 or 100 tablets.

Holder of certificate of registration

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Access to corresponding Professional Information