

1.3.2 PATIENT INFORMATION LEAFLET (CURRENT APPROVED)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Nexiam® 20 mg; Nexiam® 40 mg (Gastric-Resistant Tablet)

Nexiam® 10 mg Sachets (Granules)

NEXIAM 20 mg and 40 mg gastric-resistant tablets and NEXIAM 10 mg sachets are referred to as NEXIAM throughout this leaflet.

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 or your pharmacist.
- NEXIAM has been prescribed for you personally and you should not share your NEXIAM with other people. It may harm them, even if their symptoms are the same as yours.

1. 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).

NEXIAM 10 mg Sachets:

Each sachet contains esomeprazole magnesium trihydrate 11,1 mg (equivalent to esomeprazole 10 mg) in the form of gastro-resistant granules for oral suspension.

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.

The other ingredients in NEXIAM 10 mg sachets are:

Glycerol monostearate, hypromellose, hypromellose, magnesium stearate, methacrylic acid copolymer, polysorbate 80, sugar spheres, talc, triethyl citrate, dextrose, xanthan gum, crospovidone, citric acid, iron oxide (yellow) (E 172).

Contains sugar (sucrose).

2. WHAT NEXIAM IS USED FOR:

NEXIAM is a type of medicine called a “proton pump inhibitor” (medicines used to treat ulcers). 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 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 (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.

3. BEFORE YOU TAKE NEXIAM:

Do not take NEXIAM:

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

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 medication (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), that does not improve. Symptoms may include watery stools, stomach pain and fever.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. You should not take NEXIAM if you are pregnant or breastfeeding your baby.

Driving and using machinery:

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

Taking other medicines with NEXIAM:

Always tell your healthcare professional if you are taking any other medicine.

- 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 medication (diazepam), medicines used to prevent fitting (phenytoin), medicines used to prevent blood clotting (warfarin or clopidogrel),

intermittent claudication (cilostazol), 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 some medicines for HIV, such as atazanavir and nelfinavir, as NEXIAM may reduce the blood levels of your anti-retroviral medicine.
- 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.

4. HOW TO TAKE NEXIAM:

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.

The contents of a 10 mg sachet should be emptied into a container with a tablespoon (15 ml) of water. Stir the contents and leave for a few minutes to thicken. Stir again and

drink within 30 minutes. If any material remains after drinking, add more water, stir, and drink immediately.

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

NEXIAM should not be used in children younger than 1 year.

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 an overdose, immediately consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control 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.

5. POSSIBLE SIDE EFFECTS:

NEXIAM can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward

effects while taking this medicine, please consult your doctor, pharmacist or other health care professional 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 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.

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) sensation of burning/prickling/numbness, difficulty sleeping, feeling sleepy, dizziness, vertigo, dry mouth and peripheral swelling. Blurred vision, severe allergic reactions (swelling, anaphylactic reaction/shock), muscular pain, blood disorders (reduced number of cell 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 and inflammation in the gut (leading to diarrhoea).

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, pharmacist or other health care professional.

6. STORING AND DISPOSING OF NEXIAM:

NEXIAM 20 and 40 mg tablets:

Store at or below 30 °C.

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

NEXIAM 10 mg Sachets:

Store at or below 25 °C.

Reconstituted suspension must be taken within 30 minutes after reconstitution. Do not open the sachets until prior to use.

Keep all medicines out of the reach and sight of children.

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).

7. PRESENTATION OF NEXIAM:

NEXIAM 20 and 40 mg tablets:

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

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

NEXIAM 10 mg Sachets:

The esomeprazole pellets and excipient granules are packed into a sachet made out of 3 layers of an aluminium laminate.

NEXIAM 10 mg sachets are stored in cartons containing 28 sachets.

8. IDENTIFICATION OF NEXIAM:

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.

NEXIAM 10 mg Sachets: Pale yellow fine granules in a unit dose sachet. Brownish granules may be visible. Reconstituted suspension: The oral suspension is a thick yellow liquid containing suspended pellets.

9. REGISTRATION NUMBERS:

NEXIAM 20 mg: 35/11.4.3/0263

NEXIAM 40 mg: 35/11.4.3/0264

NEXIAM 10 mg Sachets: 42/11.4.3/1003

**10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE
CERTIFICATE:**

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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