1.3.2 PATIENT INFORMATION LEAFLET - CURRENT APPROVED

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Nexiam® 2,5 Sachets (Esomeprazole 2,5 mg) (Granules)

Nexiam® 5 Sachets (Esomeprazole 5 mg) (Granules)

NEXIAM 2,5 and 5 mg Sachets are referred to as NEXIAM throughout this leaflet.

Read all of this leaflet carefully before you give 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 your child personally and should not be shared with other people. It may harm them, even if their symptoms are the same as your child.

1. WHAT NEXIAM CONTAINS:

Each sachet of NEXIAM 2,5 mg contains 2,5 mg esomeprazole (as magnesium trihydrate).

Each sachet of NEXIAM 5 mg contains 5 mg esomeprazole (as magnesium trihydrate).

The other ingredients in NEXIAM 2,5 and 5 mg Sachets are:

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

- the decrease in acidity in the food pipe by reducing the acidity of the return flow fluid from the stomach in neonates and infants.
- the treatment of Gastro Oesophageal Reflux Disease (GORD) i.e. a condition caused by a return flow of fluid from the stomach into the food pipe confirmed by special a test (pH probe or endoscopy).

3. BEFORE YOU GIVE NEXIAM:

Do not give NEXIAM:

- If your child is allergic to esomeprazole or any of the other ingredients of NEXIAM.
- If your child is allergic to other proton pump inhibitors (e.g. pantoprazole, lanzoprazole, rabeprazole, omeprazole).

Take special care with NEXIAM:

While your child is taking 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.
  - your child begins to vomit blood or food.
  - your child passes black (blood-stained) stools. You should contact your doctor immediately.
- if your child is taking 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), intermittent claudication (cilostazol), medicines used to speed up stomach emptying (cisapride), heart problems (digoxin), treatment for tuberculosis (rifampicin), St John's Wort (hypericum performatum) (used to treat depression) and if you are using a certain type of anti-malignancy medicine (such as erlotinib or another anti-malignancy medicine from the same class).
- if your child has severe liver problems. You should discuss this with your doctor, as he/she may wish to reduce the dose.
- if your child has severe kidney problems. You should discuss this with your doctor.
- Taking esomeprazole at the same time as some medicines for HIV, such as atazanavir and nelfinavir, is not recommended.

Pregnancy and breastfeeding:

Safety during pregnancy and breastfeeding has not been established.

Before taking NEXIAM, tell your doctor if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare professional for advice before taking NEXIAM.

Only take NEXIAM on the advice of your doctor.

Driving and using machinery:

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

Giving other medicines with NEXIAM:

Always tell your healthcare professional if your child is taking any other medicine. (This includes 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 medication (diazepam), medicines used to prevent fitting (phenytoin), medicines used to prevent blood clotting (warfarin), 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 performatum) (used to treat depression), or a certain type of anti-malignancy medicine (such as erlotinib or another anti-malignancy medicine from the same class).

- Taking NEXIAM at the same time as some medicines for HIV, such as atazanavir and nelfinavir, is not recommended.
- If your child is 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 USE NEXIAM:

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

The contents of a 2,5 mg and 5 mg sachet should be emptied into a container with a teaspoon (5 ml) of non-carbonated 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. In cases where there is a need to use 2 sachets, they may be mixed in a similar way adding twice the required amount of water (10 ml). Do not use carbonated water.

The usual dose for treatment of Gastro Oesophageal Reflux Disease (GORD):

1-11 months:

NEXIAM 2,5 mg once a day for children weighing 3-5 kg.

NEXIAM 5 mg once a day for children weighing greater than 5-7,5 kg.

NEXIAM 10 mg once a day for children weighing greater than 7,5-12 kg.

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

If you give more NEXIAM than you should:

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

If you forget to give NEXIAM:

If you forget to give a dose, give it as soon as you remember. However, if it is almost time for your child's next dose, do not give the missed dose, just give the next dose on time. Do not give 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 NEXIAM are included in this leaflet. Should the general health of your child worsen or if your child experiences any untoward effects while taking NEXIAM, please consult your doctor, pharmacist or other health care professional for advice.

Frequent side effects:

Headache, stomach pain, diarrhoea, wind, nausea/vomiting, constipation.

Less frequent side effects:

Dizziness, sensation of numbness, difficulty sleeping, feeling sleepy, dry mouth, skin reactions (rash, dermatitis, itching, hives), peripheral swelling, vertigo. An increase in the amount of liver enzymes may also occur with NEXIAM - this would only be seen when a blood test is taken.

Taste disorders, inflammation in the mouth, gastrointestinal fungal infection, hair loss, sensitivity to sunlight, blood disorders (reduced number of cells in the blood ie, leukopenia and thrombocytopenia), severe allergic reactions (swelling, anaphylactic reaction/shock), low blood sodium, depression, nervousness, confusion, blurred vision, tightness in the chest, inflammation of the liver (with or without jaundice), sore joints, muscular pain, 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 and development of breasts in males, low blood magnesium and inflammation in the gut (leading to diarrhoea).

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:

Keep your sachets stored at or below 25 °C in a dry place.

Do not open sachets until you are going to use them.

Once mixed, drink within 30 minutes.

Store all medicines out of reach 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 2,5 and 5 mg Sachets are stored in cartons containing 28 sachets.

8. IDENTIFICATION OF NEXIAM:

Pale yellow fine granules in a unit sachet. Brownish granules may be visible.

Reconstituted suspension: The oral suspension is a thick yellow liquid containing suspended pellets.

9. REGISTRATION NUMBERS:

NEXIAM 2,5 Sachets: 44/11.4.3/0208

NEXIAM 5 mg Sachets: 44/11.4.3/0209

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

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