

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

NEXES OTC gastric-resistant tablets

Esomeprazole

Contains sugar: sucrose and lactose monohydrate

Read all of this leaflet carefully because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

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

1. What NEXES OTC is and what it is used for

Esomeprazole belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Esomeprazole is used to treat the following conditions:

NEXES OTC is indicated for the temporary, short-term relief of heartburn and hyperacidity subject to:

- a) a maximum daily dose of 20 milligrams
- b) a maximum treatment period of 14 days.

2. What you need to know before you take NEXES OTC

Do not take NEXES OTC

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

Warnings and precautions

Tell your doctor or health care provider before taking NEXES OTC:

- if you have been experiencing indigestion
- if you develop kidney problems
- if you have been on continuous medication for longer than a year
- if you have been taking a medication that contains clopidogrel (used in the treatment of blood clots)
- if you are due to have a specific blood test (Chromogranin A)
- If you have had previous intestinal conditions
- If you develop severe diarrhoea that has watery stools, abdominal pain and fever
- If you are taking NEXES OTC when necessary and your symptoms change
- If you have vitamin B₁₂ deficiency
- If you develop tiredness dizziness, tremor and muscle problems (hypomagnesaemia)
- If you have been diagnosed with osteoporosis (brittle bones) or are at risk of breaking your bones
- If you develop ‘butterfly rash’ with sensitivity to sunlight (subacute cutaneous lupus erythematosus)

If any of these applies to you, tell your doctor or nurse before you are given NEXES OTC.

Children and adolescents

NEXES OTC should not be used in children younger than 1 year.

Other medicines and NEXES OTC

Always tell your health care provider if you are taking any other medicine.

It is particularly important that you mention the following:

- Itraconazole, ketoconazole voriconazole used in the treatment of fungal infections
- Diazepam used in the treatment of anxiety
- Medicines used to prevent fitting (phenytoin),
- Medicines used to prevent blood clotting (warfarin or clopidogrel),
- Medicine used to help the symptoms of intermittent claudication (cilostazol),
- Medicines used to speed up stomach emptying (cisapride),
- Digoxin used in the treatment of heart problems
- Rifampicin used for the treatment of Tuberculosis
- St. John's Wort - used to treat depression, or certain type of antimalignancy medicines (such as erlotinib or another antimalignancy medicine from the same class.
- NEXES OTC should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as NEXES OTC may reduce the blood levels of your antiretroviral medicine.
- Tipranavir used to treat HIV
- Clarithromycin, an antibiotic
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer), NEXES OTC may need to be temporarily withdrawn.

Pregnancy, breastfeeding and fertility

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 NEXES OTC if you are pregnant or breastfeeding your baby.

Driving and using machines

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

NEXES OTC contains sugar in the form of sucrose and lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take NEXES OTC

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

Always take NEXES OTC exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is one capsule a day.
- Do not take more than this recommended dose of one capsule (20 mg) a day, even if you don't feel an improvement immediately.
- You may need to take the capsules for 2 or 3 days in a row before your reflux symptoms (for example, heartburn and acid regurgitation) get better.
- The treatment length is up to 14 days.
- When your reflux symptoms have completely gone you should stop taking this medicine.
- If your reflux symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

If you take more NEXES OTC than you should

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

If you forget to take NEXES OTC

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

4. Possible side effects

NEXES OTC can have side effects.

Not all side effects reported for NEXES OTC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NEXES OTC, please consult your health care provider for advice.

If any of the following happens, stop taking NEXES OTC 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).
- Rash or itching in the form of 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 reaction to NEXES OTC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Tightening of chest accompanied with severe coughing (bronchospasm)
- Loss or decreased vision
- Abdominal swelling (may be an indication of liver failure)
- Excessive sweating
- Blood in the urine (Nephritis)
- Significant reduction in the amount of urine with shortness of breath (This could be a sign of kidney failure)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Stomach pain
- Diarrhoea
- Nausea/Vomiting
- Constipation
- Headache

Less Frequent side effects:

- Muscle weakness/pain
- Fever
- Development of breast tissue in males
- Joint pain
- Hair loss
- Dry mouth
- Inflammation of the mouth and lips
- Dizziness
- Blurred vision
- Tingling sensation
- Loss of balance
- Taste disturbance
- Sleepiness
- Inability to sleep
- Confusion
- Depression
- Agitation
- Hallucination
- Low white blood cell count

Side effects of which frequency is unknown:

- Decreased levels of calcium
- Decreased levels of magnesium
- “Butterfly rash” that lasts hours – days

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you/your child get/s side effects, talk to your/your child's doctor or pharmacist. 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 or to Acino Pharma via email on drugsafety_ZA@acino.swiss. By reporting side effects, you can help provide more information on the safety of NEXES OTC

5. How to store NEXES OTC

- Store all medicines out of reach of children.
- Protect from light / moisture
- Do not use after the expiry date stated on the label
- Do not store above 30 °C
- 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 NEXES OTC contains

- The active substance is Esomeprazole Magnesium dihydrate.
- The other ingredients are:
colloidal anhydrous silica, copovidone K-28, crospovidone (E1202), diethyl phthalate, ethyl cellulose (E462), ferric oxide red (E172) Hypromellose, light magnesium oxide (E530), macrogol 8000, magnesium stearate (E572), methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent, povidone K-90, silicified microcrystalline cellulose (microcrystalline cellulose and colloidal anhydrous silica), Starlac (lactose monohydrate and maize starch), sugar spheres (sucrose and maize starch), talc (purified) (E553b), titanium dioxide (E171), imprinting ink: black iron oxide (E172) and Shellac glaze (E904).

What NEXES OTC looks like and contents of the pack

NEXES OTC

Brick red coloured, round shape, biconvex, film-coated tablet imprinted with "20" on one side with black ink and plain on the other side.

NEXES OTC tablets are packed in following packs:

Aluminum – Aluminum blisters:

Alu-Alu blister pack using aluminium foil with heat seal lacquer and cold formable blister aluminium foil. The blister strips will be packed in an outer carton.

Pack size: 14 or 28's.

HDPE containers:

HDPE container pack using High – Density Polyethylene [HDPE] container of neck finish and CT closure with induction sealing wad.

Pack size: 14, 28, 56, or 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

106, 16th Road

Midrand

1686

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Access to the corresponding Professional Information

The professional information for NEXES OTC can be accessed by scanning the QR code below: