Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product name:** Nexilok 20 **Dosage form & strength:** Each gastro-resistant tablet contains 21,75 mg esomeprazole magnesium dihydrate equivalent to 20 mg esomeprazole base

APPROVED PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S2

NEXILOK 20, gastro-resistant tablets

Esomeprazole

NEXILOK 20: contains sugar (sucrose 5,65 mg per tablet) and 0,6 mg sodium per tablet

Read all of this leaflet carefully before you start taking NEXILOK:

- Keep this leaflet. You may need to read it again.
- Do not share NEXILOK with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT IS IN THIS LEAFLET:

1. WHAT NEXILOK IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEXILOK

3. HOW TO TAKE NEXILOK

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE NEXILOK

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1. WHAT NEXILOK IS AND WHAT IT IS USED FOR:

Esomeprazole (as contained in NEXILOK) belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

NEXILOK is indicated for the temporary short-term relief of heartburn and hyperacidity. Heartburn is the painful sensation in the chest rising up to your throat.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEXILOK:

Do not take NEXILOK:

- if you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of NEXILOK
- if you are taking medication for HIV treatment (atazanavir or nelfinavir).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions:

Take special care with NEXILOK if:

- You have had a stomach ulcer or stomach surgery in the past.
- You have been taking treatment continuously for reflux or heartburn for 4 or more weeks.
- You have jaundice (yellowing of skin or eyes) or severe liver problems.
- You have severe kidney problems. Proton pump inhibitor medicines, such as NEXILOK, may rarely cause interstitial nephritis which can lead to inflammation that affects the tubules of the kidneys and the tissues that surround them. This condition may progress to kidney failure and is not necessarily reversed when treatment is discontinued.
- You need to take a non-prescription indigestion or heartburn remedy treatment every day.
- You have ever had a skin reaction after treatment with a medicine similar to NEXILOK that reduces stomach acid.
- You suffer from any condition that reduces absorption of vitamin B12 or have low levels of vitamin B12

Tell your doctor immediately before or after taking this medicine, if you notice any of the following symptoms:

- You lose a lot of weight for no reason.
- You have problems or pain when swallowing.
- You get stomach pain or signs of indigestion such as nausea, fullness, bloating especially after food intake.
- You begin to vomit food or blood, which may appear as dark coffee grounds in your vomit.
- You pass black stools (blood-stained faeces).

- You have severe or persistent diarrhoea; NEXILOK has been associated with a small increased risk of infectious diarrhoea. This diarrhoea may be caused by an infection (Clostridium difficile) in your intestines. Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.
- You notice symptoms such as excessive tiredness, involuntary muscle contractions, delirium, convulsions, dizziness and erratic heartbeat. These may be due to low magnesium levels.
- If you experience serious skin rashes after flu-like symptoms such as fever, headache and body ache. The rash may cover large parts of the body accompanied by blistering and peeling of the skin. If at any time during the treatment (even after several weeks) you develop a rash or any of these symptoms associated with the skin, stop taking this medicine and contact your doctor immediately.

Subacute chronic lesions on the skin and mucous membranes (SCLE):

Proton pump inhibitor medicines, such as NEXILOK, are associated with very infrequent cases of this condition. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by pain in joints, the patient should seek medical help immediately and the healthcare professional should consider stopping NEXILOK. The condition after previous treatment with a proton pump inhibitor may increase the risk of the condition with other proton pump inhibitors.

Children:

NEXILOK should not be used in children younger than 18 years of age.

Other medicines and NEXILOK:

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

Do not take this medicine if you are also taking a medicine containing nelfinavir or atazanavir (used to treat HIV infection).

Do not take this medicine with other medicines that limit the amount of acid produced in your stomach such as proton pump inhibitors (PPI's).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Itraconazole, ketoconazole voriconazole used in the treatment of fungal infections since NEXILOK may affect its concentration in your body.
- Diazepam used in the treatment of anxiety.
- Medicines used to prevent fits (phenytoin).
- Medicines used to prevent blood clotting (warfarin). It may be necessary to monitor your blood coagulation more often.
- Clopidogrel to prevent blood clots. NEXILOK and clopidogrel should not be used together as the effect of clopidogrel may be reduced.
- Medicine used to treat pain in your legs when you walk which is caused by an insufficient blood supply (cilostazol).
- Medicines used to speed up stomach emptying, indigestion and heartburn (cisapride).
- Digoxin used in the treatment of heart problems.
- Rifampicin used for the treatment of Tuberculosis.
- St. John's Wort (Hypericum perforatum) - used to treat depression.
- Erlotinib (used to treat cancer).
- Saquinavir 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), NEXILOK may need to be temporarily withdrawn.
- Citalopram, imipramine or clomipramine (used to treat depression, as a muscle relaxant or in epilepsy).
- Tacrolimus (used in organ transplantation).

NEXILOK with food and drink:

NEXILOK can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking NEXILOK. You should not take NEXILOK if you are pregnant or breastfeeding your baby.

Driving and using machines:

NEXILOK may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery. You are advised to exercise caution when driving or using machines.

NEXILOK contains sugar in the form of sucrose:

Sucrose may have an effect on the control of your blood sugar if you have diabetes mellitus.

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

NEXILOK contains sodium:

NEXILOK contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE NEXILOK:

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

Always take NEXILOK exactly as described in this leaflet or as your doctor, or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of NEXILOK is one tablet a day.

- Do not take more than this recommended dose of one tablet (20 mg) a day, even if you don’t feel an improvement immediately.
- The treatment length is up to 14 days.
- When your symptoms have completely gone you should stop taking this medicine.
- If your symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

Taking this medicine:

- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you have trouble swallowing the tablets:

If you have trouble swallowing the tablets:

- Put them into half a glass of still (non-fizzy) water. Do not use any other liquids.
- Stir until the tablets break up (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.

If you cannot swallow at all, the tablet can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach (‘gastric tube’).

Your doctor will tell you how long your treatment with NEXILOK will last. If you have the impression that the effect of NEXILOK is too strong or too weak, tell your doctor or pharmacist.

If you take more NEXILOK than you should:

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

If you forget to take NEXILOK:

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:

NEXILOK can have side effects.

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

If any of the following happens, stop taking NEXILOK 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).
- unusual bleeding or bruising, black tarry stools; blood in urine or stools; pinpoint red spots on skin.
- 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' or drug reaction with eosinophilia and systemic symptoms (DRESS)
- yellow skin, dark urine and tiredness which can be symptoms of liver problems.
- blood disorders such as the lack of white blood cells (agranulocytosis) leading to immune deficiency, associated with sore throat, fever or chills, cough or hoarseness; lower back or side pain; painful or difficult urination.

These are all very serious side effects. If you have them, you may have had a serious reaction to NEXILOK. 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:

- headache
- diarrhoea
- stomach pain
- constipation
- flatulence
- nausea, vomiting
- skin rashes

Less frequent:

- severe diarrhoea characterised by watery stools, stomach pain, fever (Clostridium difficile associated diarrhoea)
- muscle weakness/pain
- fever
- development of breast tissue in males
- joint pain
- fracture of hip, wrist or spine
- hair loss
- dry mouth
- inflammation of the mouth and lips
- dizziness
- blurred vision
- tingling sensation

- loss of balance
- sleepiness
- inability to sleep
- reversible confusion
- depression
- agitation
- kidney problems with symptoms such as decreased urine, increase or decrease in urination frequency, swelling of the feet and ankles, nausea, fatigue, shortness of breath, loss of appetite or high blood pressure
- fatigue

Side effects of which the frequency is unknown:

- low white blood cell count; low levels of red blood cells, white blood cells and platelets
- decreased levels of calcium
- decreased levels of magnesium
- hallucination and aggression
- taste disturbance
- inflammation of the large intestine (microscopic colitis)
- brain dysfunction due to liver dysfunction, liver failure
- renal failure
- “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 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 NEXILOK.

5. HOW TO STORE NEXILOK:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not store above 30 °C.

Store in the original package (blister) in order to protect from moisture.

Do not use after the expiry date stated on the label.

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 NEXILOK contains:

The active substance is esomeprazole magnesium dihydrate.

Each NEXILOK 20 mg tablet contains 20 mg of esomeprazole (corresponding to 21,75 mg esomeprazole magnesium dihydrate).

The other ingredients are:

Pellets: glycerol monostearate 40-55, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1), microcrystalline cellulose, polysorbate 80, sugar spheres, talc, triethyl citrate.

Tablet core: crospovidone (Type A), macrogol 6000, microcrystalline cellulose, povidone K-29/32, sodium stearyl fumarate.

Tablet coating: Opadry Pink 03B34284/5 consisting of hypromellose, titanium dioxide (E171), macrogol/PEG 400, red iron oxide (E172), yellow iron oxide (E172).

What NEXILOK looks like and contents of the pack:

NEXILOK 20 tablets are light pink, elliptically shaped, biconvex enteric-coated tablets, 6,55 x 13,6 mm.

OPA/Aluminium/PVC-Aluminium foil blisters.

Pack sizes: 7 or 14 tablets

Not all pack sizes may be marketed.

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Holder of Certificate of Registration:

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This leaflet was last revised in:

30 June 2026

Registration/Application number:

NEXILOK 20: 46/11.4.3/0506