Teva Pharmaceuticals (Pty) Ltd.	**Product:** **Lokit OTC** **Dosage Form:** **Capsule** **Strength**: Omeprazole 20 mg
Reg. No.: 54/11.4.3/0021	

Patient Information Leaflet

SCHEDULING STATUS: **S2**

LOKIT OTC, 20 mg hard gelatine capsules

Omeprazole

Contains sugar (sucrose 80,02 mg per capsule)

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

LOKIT OTC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use LOKIT OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOKIT OTC with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

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

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

3. How to take LOKIT OTC

4. Possible side effects

5. How to store LOKIT OTC

6. Contents of the pack and other information

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

LOKIT OTC contains the active substance omeprazole. It belongs to a group of medicines called proton pump inhibitors. They work by reducing the amount of acid that your stomach produces.

LOKIT OTC is used for temporary, short-term relief of heartburn and hyperacidity.

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

Do not take LOKIT OTC

- if you are hypersensitive (allergic) to omeprazole or any of the other ingredients of LOKIT OTC (listed in section 6)
- if you are taking a medicine containing nelfinavir (used for HIV infection)
- Safety in pregnancy and lactation has not been established.

Warnings and precautions

Take special care with LOKIT OTC if:

- You loose a lot of weight for no reason and have problems swallowing
- You get stomach pain or indigestion
- You begin to vomit food or blood
- You pass black stools (blood-stained faeces)
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You experience tiredness, involuntary contraction of muscles, mental confusion, fits, dizziness, heart rhythm problems (hypomagnesaemia)
- You are elderly and are at risk of osteoporosis
- You have ever had a skin reaction after treatment with a medicine similar to

LOKIT OTC that reduces stomach acid.

- You are due to have a specific blood test (Chromogranin A).
- You have severe liver problems.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with LOKIT OTC. Remember to also mention any other ill-effects like pain in your joints.

Children

There is very limited experience with the use of LOKIT OTC in children.

Other medicines and LOKIT OTC

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

Do not take LOKIT OTC if you are taking a medicine containing nelfinavir (used to treat HIV infection).

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

- Atazanavir, saquinavir (used to treat HIV infection)
- Digoxin (used to treat heart problems)
- Clopidogrel (used to prevent blood clots (thrombi))
- Ketoconazole, posaconazole, itraconazole or voriconazole (used to treat infections caused by a fungus)
- Erlotinib (used to treat different types of cancer)

- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking LOKIT OTC
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Cilostazol (used to treat intermittent claudication)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking LOKIT OTC
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer and inflammatory conditions) – if you are taking a high dose of methotrexate, you doctor may temporarily stop your LOKIT OTC treatment
- Tacrolimus (in cases of organ transplantation)
- Clarithromycin (an antibiotic) unless you are being treated with this medicine for *H.pylori*
- Rifampicin (used to treat tuberculosis)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)

LOKIT OTC with food and drink

LOKIT OTC can be taken with or without food.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking LOKIT OTC.

Safety in breastfeeding has not been established. LOKIT OTC is excreted in breast milk.

Driving and using machines

Side effects such as dizziness and visual disturbances may occur with the use of LOKIT OTC.

It is not always possible to predict to what extent LOKIT OTC may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which LOKIT OTC affects you.

LOKIT OTC contains sucrose

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

3. How to take LOKIT OTC

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

Always take LOKIT OTC exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

- Take one 20 mg capsule in the morning, swallowed whole with a glass of liquid.
- Do not chew or crush the capsule.
- The maximum daily dose is 20 mg.
- Do not take for longer than 14 days.
- If your symptoms do not clear up after 14 days, contact your doctor.

If you take more LOKIT OTC 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 LOKIT OTC

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LOKIT OTC can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes also called jaundice.

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

Less frequently:

- blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.

- 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'
- severe kidney problems (interstitial nephritis). You may pass little or no urine, have cloudy urine or blood in the urine or have severe pain in the lower back.

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:

- headache
- diarrhoea, nausea, constipation, stomach pain
- vomiting, wind (flatulence), benign polyps in the stomach

Less frequent side effects:

- low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps
- feeling agitated, confused, angry or depressed
- disturbed sleep (insomnia), hallucinations
- dizziness, drowsiness, tingling feelings such as pins and needles, taste changes
- blurred vision
- spinning feeling (vertigo)
- swelling of the feet and ankles
- sudden wheezy feeling or short of breath (bronchospasm)
- dry mouth
- an inflammation of the inside of the mouth

- an infection called “thrush” which can affect the oesophagus and gut and is caused by a fungus
- severe liver problems leading to liver failure and inflammation of the brain
- increased liver enzymes
- hives, inflammation of the skin, skin rash on exposure to sunshine
- fluid-filled blisters, hair loss, skin infection
- physical weakness and lacking energy, joint pains (arthralgia)
- muscle pains (myalgia), muscle weakness, muscle tissue disease
- enlarged breasts in men
- increased sweating, a general feeling of discomfort, illness, swelling of your lower legs or hands

Side effects with unknown frequency

- low levels of magnesium which can also lead to a reduction in potassium or calcium levels in the blood
- inflammation in the gut (leading to diarrhoea)
- rash, possibly with pain in the joints

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LOKIT OTC.

5. How to store LOKIT OTC

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C, protected from light and moisture.

Store in the original package until required for use.

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 LOKIT OTC contains

The active substance of LOKIT OTC is omeprazole.

The other ingredients are:

Capsule content - Hypromellose, methacrylic acid-ethyl acrylate copolymer, povidone, sodium hydroxide (for pH-adjustment), sodium lauryl sulphate, sodium starch glycolate, sugar spheres (sucrose and corn starch), talc, titanium dioxide triethyl citrate, trisodium phosphate.

Capsule shell – gelatine, eritrosine (E-127), Indigo carmine (E-132), Quinoleine yellow (E-104), titanium dioxide (E1-171), water.

Printing ink - ethyl alcohol anhydrous, isopropyl alcohol, N-butyl alcohol, polyvinylpyrrolidone, propylene glycol, shellac, sodium hydroxide, titanium dioxide (E 171).

What LOKIT OTC looks like and contents of the pack

LOKIT OTC: Opaque blue cap and opaque orange body, number 2 hard gelatine capsules. The capsules have been marked using white ink with the letter “O” in the cap and the number “20” in the body. The capsules are filled with white to beige micropellets.

LOKIT OTC hard gelatine capsules are packaged in blisters that are composed of:

- Hard aluminum sheet of 20 µm + heat-seal lacquer to PVC or PVDC and
- Polymide sheet of 25 µm + aluminum of 45 µm + PVC of 60 µm.

LOKIT OTC hard gelatine capsules are packaged in:

- White high-density polyethylene bottle with a white polypropylene cap provided with a compartment for silica gel desiccant.

The pack sizes available are 7, 14 capsules.

LOKIT OTC capsules is packaged in an outer cardboard carton.

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This leaflet was last revised in

05 October 2021

Registration/Application number

Lokit OTC: 54/11.4.3/0021