

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LOKIT OD 20 & LOKIT OD 40, 20 and 40 mg hard gelatine capsules

Omeprazole

LOKIT OD 20 contains sugar (sucrose 80,02 mg per capsule) and LOKIT OD 40 contains sugar (sucrose 160,05 mg per capsule)

Read all of this leaflet carefully before you start taking LOKIT OD.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- LOKIT OD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

- 1. WHAT LOKIT OD IS AND WHAT IT IS USED FOR**
- 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOKIT OD**
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1. WHAT LOKIT OD IS AND WHAT IT IS USED FOR:

LOKIT OD 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 OD is used to treat the following conditions:

- Reflux oesophagitis. This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Ulcers which are infected with bacteria called *Helicobacter pylori*. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOKIT OD:

Do not take LOKIT OD:

- if you are hypersensitive (allergic) to omeprazole or any of the other ingredients of LOKIT OD.
- 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 OD if:

- You lose 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 have ever had a skin reaction after treatment with a medicine similar to LOKIT OD that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).
- You have severe liver problems.

Taking a proton pump inhibitor like omeprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

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 OD. Remember to also mention any other ill-effects like pain in your joints.

If you take LOKIT OD on a long-term basis (longer than 1 year) your doctor will monitor you. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Children:

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

Other medicines and LOKIT OD:

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

Do not take LOKIT OD 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 OD.
- 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 OD.
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer and inflammatory conditions) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your LOKIT OD 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 OD with food and drink:

LOKIT OD 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 OD.

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

Driving and using machines:

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

It is not always possible to predict to what extent LOKIT OD 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 OD affects you.

LOKIT OD contains sucrose.

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

3. HOW TO TAKE LOKIT OD:

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

Always take LOKIT OD exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

To treat ulcers in the upper part of the intestine (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 to 4 weeks.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day.

To treat ulcers in the stomach or reflux oesophagitis:

- The recommended dose is 20 mg once a day for 4 to 8 weeks.
- If the ulcers do not fully heal, your doctor may increase the dose to 40 mg once a day.

To treat symptoms of GORD such as heartburn and acid regurgitation:

- The recommended dose is 20 mg once a day.
- Your doctor will investigate further if your symptoms have not been controlled.

To treat too much acid in the stomach caused by a growth in the pancreas:

- The recommended dose is 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Your doctor will tell you how long your treatment with LOKIT OD will last. Do not stop treatment early because you feel better.

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

If you take more LOKIT OD 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 OD:

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

If you stop taking LOKIT OD:

Do not stop taking LOKIT OD without first talking to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

LOKIT OD can have side effects.

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

If any of the following happens, stop taking LOKIT OD 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 OD. 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
- severe kidney problems (interstitial nephritis)
- 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 OD.

5. HOW TO STORE LOKIT OD:

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 OD contains:

The active substance of LOKIT OD 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 titrate, 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 OD looks like and contents of the pack:

LOKIT OD 20: Capsules of hard gelatine, number 2, with an opaque blue cap and opaque orange body. 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 micro pellets.

LOKIT OD 40: Capsules of hard gelatine, number 0, with an opaque blue cap and opaque orange body. The capsule has been marked using white ink with the letter “O” in the cap and the number “40” in the body. The capsules are filled with white to beige micro pellets.

LOKIT OD 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
- Polyimide sheet of 25 µm + aluminum of 45 µm + PVC of 60 µm.

LOKIT OD 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, 28 or 30 capsules.

LOKIT OD capsules are packaged in an outer cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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