PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

KLARIZON 250 (clarithromycin 250 mg) Tablets

KLARIZON 500 (clarithromycin 500 mg) Tablets

Clarithromycin

Sugar free

Read all of this this leaflet carefully before you start taking KLARIZON tablets.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- KLARIZON 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 KLARIZON is and what it is used for
2. What you need to know before you take KLARIZON
3. How to take KLARIZON
4. Possible side effects
5. How to store KLARIZON
6. Contents of the pack and other information

1. What KLARIZON is and what it is used for

KLARIZON belongs to a group of medicines called macrolide antibiotics. Antibiotics stop the growth of

bacteria (bugs) that cause infections. KLARIZON contains the active ingredient, clarithromycin. KLARIZON is used to treat bacterial infections in many different parts of the body.

Your doctor will prescribe KLARIZON to treat the following infections such as:

- chest infections (like pneumonia and bronchitis)
- infections of the middle ear
- tonsils
- skin and infections of the throat and sinuses
- KLARIZON in combination with another antibiotic, amoxicillin and a specific medicine indicated to reduce stomach acid can also be used for the treatment of a duodenal ulcer when this ulcer is caused by a bacteria, *Helicobacter pylori.*

Your doctor will tell you what you are being treated for.

2. What you need to know before you take KLARIZON

Do not take KLARIZON:

- If you are hypersensitive (allergic) to clarithromycin, any macrolide antibiotics or any of the ingredients of KLARIZON (listed in section 6).
- If you are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies), domperidone or cisapride (for stomach problems) or pimozide (for mental health problems), as combining these medicines can sometimes cause serious disturbances in heart rhythm.
- If you are taking certain antipsychotic medicines, such as quetiapine, cariprazine, and aripiprazole (for mental problems), it can make the levels of these antipsychotic medicines in your blood go up. This can lead to severe side effects (see section 'Other medicines and KLARIZON).
- Have a history of QT prolongation (an abnormality if the electrocardiogram (ECG)) or an irregular heartbeat (ventricular cardiac dysrhythmia).

- If you are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine.
- If you are taking oral midazolam (a sedative).
- If you are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina).
- If you are taking lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood).
- If you are taking colchicine (usually taken for gout).
- If you have hypokalaemia (a condition characterised by low levels of potassium in the blood).
- If you have severe liver disease with kidney disease.
- If you suffer from porphyria.

Warnings and precautions

Take special care with KLARIZON:

- If you have kidney and severe liver disease. You may have an increased chance of side effects.
- If you experience rhabdomyolysis, which is a condition in which skeletal muscle tissue dies, releasing substances into the blood that cause kidney failure.
- If you develop severe or prolonged diarrhoea (pseudomembranous colitis), which may have blood or mucus in it, during or after taking KLARIZON, contact your doctor immediately.
- If you have, or have had, heart problems (e.g., heart disease, heart failure, an unusually slow heart rate) or abnormally low levels of magnesium in the blood (hypomagnesaemia).
- If you have pneumonia (serious lung infection with fever, chills, shortness of breath, cough, phlegm or coughing blood).
- In the event of severe acute hypersensitivity reactions, such as anaphylaxis, Stevens-Johnson Syndrome, and toxic epidermal necrolysis, KLARIZON therapy should be discontinued immediately and appropriate

treatment should be urgently initiated.

- If you suffer from blood clots or currently using blood thinning medicine.
- If you have a weak immune system (immunocompromised) you may experience nausea, vomiting, irregular taste, stomach pain, runny stomach, rash, flatulence (gas), headache, hearing disturbance, irregular liver test results and irregular low white blood cell and platelet counts or difficulty breathing, restlessness and dry mouth.

Other medicines and KLARIZON

Always tell your healthcare professional if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

The following medication may interact with clarithromycin and therefore you should notify your doctor or healthcare professional if you are taking medicines that contains any of the following before taking KLARIZON:

- Terfenadine or astemizole (used to treat hay fever or allergies) cisapride or domperidone (used to treat stomach disorders) or pimozide (used to treat certain mental disorders) as combining these medicines can sometimes cause serious disturbances in heart rhythm.
- Ergot alkaloids, e.g., ergotamine or dihydroergotamine used to treat migraines.
- Midazolam to treat disorders or insomnia (difficulty sleeping) is contraindicated.
- Atorvastatin, rosuvastatin, lovastatin or simvastatin commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood). Statins can cause rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.
- Carbamazepine, valproate, phenobarbital or phenytoin used to treat for epilepsy (fits).

- Rifabutin, rifampicin, rifapentine, fluconazole or itraconazole used to treat bacterial infections.
- Etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir or saquinavir used to treat HIV.
- Warfarin, rivaroxaban or apixaban also known as blood thinners used to treat blood clots.
- Quetiapine, cariprazine, or aripiprazole used to treat certain mental/mood disorders.
- Sildenafil, tadalafil or vardenafil used to treat erectile dysfunction.
- Tacrolimus used to treat eczema.
- Sirolimus used to prevent rejection of kidney transplant.
- Vinblastine used to treat certain types of cancer.
- Theophylline used to treat asthma.
- Nateglinide or repaglinide used to treat Type 2 diabetes.
- Omeprazole used to treat heart burn or stomach ulcers.
- Tolterodine used to treat overactive bladder.
- Colchicine used to treatment of gout.
- Digoxin, quinidine, disopyramide, calcium channel blockers (verapamil, amlodipine, diltiazem) used to treat irregular heartbeat.
- Itraconazole used to treat fungal infections.
- Contraceptives used to prevent pregnancy.

KLARIZON with food and drink

KLARIZON may be taken with or without meals.

Pregnancy, breastfeeding and fertility

Safety and effectiveness in pregnancy and breastfeeding have not been established.

KLARIZON is excreted in the breast milk.

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 KLARIZON.

Driving and using machines

It is not always possible to predict to what extent KLARIZON may interfere with the daily activities of a patient. patients should ensure that they do not engage in the above activities until they are aware of the measure to which KLARIZON affects them. KLARIZON may make you dizzy, drowsy, confused or disorientated.

Important information about some of the ingredients of KLARIZON

KLARIZON contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take KLARIZON

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

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

KLARIZON may be taken with food or milk or on an empty stomach.

- The usual dose in adults is 250 mg twice a day, which could be increased to 500 mg twice a day for more severe infections.
- If you suffer from severe renal impairment, your doctor will reduce the dosage of KLARIZON by half e.g., 250 mg once daily or 250 mg twice daily for severe infections.
- For peptic ulcer caused by the bacteria *Helicobacter pylori* (in combination with amoxicillin and a medicine that specifically reduce stomach acid): 500 mg twice daily for 7 to 10 days.
- Prevention of infections in AIDS patients with very low CD4 cells, KLARIZON 500 mg twice daily.

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

pharmacist.

If you take more KLARIZON than you should

Ingestion of large amounts of KLARIZON can be expected to produce gastrointestinal symptoms such as nausea, vomiting, diarrhoea, abdominal pain or cramps, tenderness, severe watery diarrhoea which may also be bloody.

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 KLARIZON

If you miss a dose do not worry, take it as soon as you remember. Do not take two doses together. If it is almost time for your next dose, wait until then.

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

If you stop taking KLARIZON

KLARIZON is an antibiotic and the course should be completed. Stopping your treatment early might lead to ineffectiveness of the treatment and resistance to bacteria making treatment in the future more difficult.

4. Possible side effects

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Severe skin reactions such as painful blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).
- A red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis).
- A rare allergic skin reactions which cause severe illness with ulceration of the mouth, lips and skin which causes severe illness with rash, fever and inflammation of internal organs (DRESS).

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

- irregular or fast heartbeat;
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage);
- fits (convulsions);
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems;
- abdominal cramps or pain, tenderness, severe, watery diarrhoea which may also be bloody, fever.

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:

- difficulty sleeping
- headache, taste disturbances

- stomach discomfort or pain, diarrhoea, nausea and vomiting
- disturbed digestion and presence of excessive gas
- irregular liver function test
- rash
- excessive sweating

Less frequent side effects:

- irregular blood cells that may cause fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal
- oral or vaginal 'thrush' (a fungal infection)
- inflammation of the stomach and intestines
- lack or loss of appetite
- anxiety, nervousness
- drowsiness, dizziness or shaking
- ringing in the ears, vertigo or hearing loss
- nosebleed
- inflammation of the lining of the gullet (oesophagus) and lining of the stomach
- bloating, constipation, wind, burping
- dry mouth
- anal pain
- inflammation of the tongue
- painful swelling and sores inside the mouth
- situation where the bile (fluid make by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis)

- increased liver enzymes
- inflammation of the skin characterised by the presence of the bullae which are filled with fluid, itchy and painful rash, hives
- muscle spasms or muscle pain
- raised abnormal kidney and liver function blood test and raised blood tests
- feeling weak, tired and having no energy, chills

Frequency unknown:

- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- a bacterial infection of the skin's outer layers
- depression
- seeing and hearing things that are not there
- abnormal dreams or nightmares
- mood of excitement, over activity and uninhibited behaviour
- tingling feeling in hands and feet also known as “pins and needles”
- loss of taste or smell or inability to smell properly
- deafness
- visual impairment or blurred vision
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- loss of blood (haemorrhage)
- low blood sugar levels
- tooth and tongue discolouration
- inflammation of the pancreas

- acne
- change in the levels of products produced by the kidney, inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination)
- abnormal urine colour
- blood is taking longer to clot, bleeding or clotting disorder.

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 "**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 KLARIZON.

5. How to store KLARIZON

Store at or below 25 °C and protect from light.

Keep the blisters in the carton until required for use.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not use after the expiry date stated on the blister or carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What KLARIZON contains

The active substance is clarithromycin 250 mg or 500 mg respectively per tablet.

The other ingredients are:

Uncoated tablet:

Colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, povidone K25, stearic acid, talc.

Film-coating:

Hydroxypropylmethyl cellulose, hydroxypropyl cellulose, propylene glycol, sorbic acid, sorbitan mono-oleate, titanium dioxide, quinoline yellow lake, vanilla dry flavour.

What KLARIZON looks like and contents of the pack

KLARIZON 250: Yellow, film coated, oval-shaped, biconvex tablets, scored on one side (14,5 mm).

KLARIZON 500: Yellow, film coated, oval-shaped, biconvex tablets, scored on one side (19,0 mm).

KLARIZON 250: PVC/PVDC blister packs containing 10 or 14 tablets, packed into an outer carton together with a patient information leaflet.

KLARIZON 500: PVC/PVDC blister packs containing 10 or 14 tablets, packed into an outer carton together with a patient information leaflet.

Holder of Certificate of Registration

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This leaflet was last revised in

21 November 2023

Registration number

KLARIZON 250: A38/20.1.1/0724

KLARIZON 500: A38/20.1.1/0725