SCHEDULING STATUS

S4

KLARITHRAN 500 TABLETS

Each film coated tablet contains

Clarithromycin 500 mg

Sugar free

KLARITHRAN 125 mg/5 ml

Clarithromycin	125 mg
Sodium benzoate (as preservative)	0,2 % m/v

Contains Sugar:

Sucrose	2,929 g/5 ml
Contains Aspartame	20 mg

KLARITHRAN 250 mg/5 ml

Clarithromycin	250 mg
Sodium benzoate (as preservative)	0,2 % m/v

Contains Sugar

Sucrose	2,508 g/5 ml
Contains Aspartame	20 mg

Read all of this leaflet carefully before you start taking KLARITHRAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- KLARITHRAN 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 the leaflet

1. What KLARITHRAN is and what it is used for

KLARITHRAN belong to broad and medium spectrum antibiotics.

KLARITHRAN is are used to treat bacterial infections, such as chest infections e.g. bronchitis and pneumonia, infections of throat and sinuses and skin infections.

2. What you need to know before you take KLARITHRAN

Do not take KLARITHRAN:

- If you are hypersensitive (allergic) to clarithromycin or other macrolide antibiotics (erythromycin or azithromycin) or any of the other ingredients of KLARITHRAN (listed in section 6).

• If you are taking ergot alkaloids, such as ergotamine or dihydroergotamine (medicines used to treat migraines).

• If you are taking oral midazolam (a medicine used to treat anxiety and insomnia).

• If you are taking a medicine containing lomitapide (a medicine, use to treat high cholesterol).

- If you are taking astemizole or terfenadine (medicines used to treat allergies), cisapride or domperidone (a medicine used to treat gastrointestinal tract disorders), pimozide (a medicine used to treat mental disorders), because they may cause serious disturbances in heart rhythm when taken together with KLARITHRAN.

• If you have or anyone in your family has had a history of heart rhythm disturbances (ventricular cardiac arrhythmias, including torsades de pointes) or abnormal electrocardiogram results (ECG, measurement of the electrical activity of the heart) called “long QT syndrome”.

• If you are taking ticagrelor (a medicine that prevents bold clotting) or ivabradine or ranolazine (a cardiac medicines).

• If you are taking lovastatin or simvastatin (statin medicines used to lower blood cholesterol) as the combination with KLARITHRAN can cause rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage) and myopathy (muscle pain or muscle weakness).

- If you are taking quetiapine, cariprazine, and aripiprazole used to treat certain mental/mood disorders.
- If you are taking colchicine (a medicine used to treat gout).

• If you have been diagnosed with low level of potassium or magnesium in the blood (hypokalaemia or hypomagnesaemia).

• If you have been diagnosed with severe liver failure with kidney failure.

• If you suffer from porphyria.

Warnings and precautions

Take special care with KLARITHRAN

- If you have or have had any liver or kidney problems.
- If you are taking rifabutin and/or rifampicin as the combination will cause a decrease of KLARITHRAN in your blood. Co-administration has been reported to cause a higher incidence of uveitis, an inflammation of part of the eye compared to when rifabutin is taken alone.
- If you are taking theophylline, a medicine used to open your airways to help you breath better.
- If you develop severe or prolonged diarrhoea (pseudomembranous colitis), which may have blood or mucus in it, during or after taking KLARITHRAN, contact your doctor

immediately. In this situation, you should not take medicines that stop or slow bowel movement.

- If you are taking colchicine (a medicine used to treat gout).
- If you are taking certain medicines called benzodiazepines (e.g. midazolam, triazolam) sed as sedatives and calmatives.
- 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 or potassium the blood.
- 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, KLARITHRAN therapy should be discontinued immediately and appropriate treatment should be urgently initiated.
- If you are taking certain medicines called statins (used to lower blood cholesterol) and you experience rhabdomyolysis, which is a condition in which skeletal muscle tissue dies, releasing substances into the blood that cause kidney failure.
- if you are taking certain medicines to lower blood sugar (sulphonylureas used in the treatment of type II diabetes) or insulin.
- If you are currently using a blood thinning medicine (e.g. warfarin).

- 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.

Children

Safety and efficacy in infants under 6 months of age has not been established.

KLARITHRAN is not suitable for use in children less than 12 years of age.

Other medicines and KLARITHRAN

Always tell your health care provider 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 **KLARITHRAN:**

- astemizole and terfenadine (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
- alprazolam, midazolam, temazepam, nitrazepam, lorazepam or triazolam used to treat anxiety disorders or insomnia (difficulty sleeping)
- 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.
- ticagrelor, ranolazine (a medicine used to treat heart and circulatory diseases)
- warfarin, coumarin, rivaroxaban, apixaban, edoxaban or any other anti-clotting medicines
- carbamazepine, valproate, phenobarbital or phenytoin used to treat for epilepsy (fits)

- digoxin, quinidine, disopyramide (used to treat heart failure)
- rifabutin, rifampicin and rifapentine used to treat bacterial infections
- etravirine, efavirenz, nevirapine, ritonavir, atazanavir or saquinavir used to treat HIV
- theophylline (a medicine used to treat asthma)
- zidovudine (clarithromycin decreases the concentration of zidovudine and should be taken at least 4 hours apart)
- fluconazole or itraconazole (used to treat fungal infections)
- cilostazol (for poor circulation)
- ciclosporin and tacrolimus (medicines affecting the immune system)
- sirolimus used to prevent rejection of kidney transplant
- ibrutinib and vinblastine (for cancer treatment)
- methadone (used in the treatment of opioid addiction)
- methylprednisolone (a corticosteroid)
- quetiapine, cariprazine, and aripiprazole used to treat certain mental/mood disorders
- nateglinide or repaglinide used to treat Type 2 diabetes.
- omeprazole used to treat heart burn or stomach ulcers.
- sildenafil, tadalafil or vardenafil used to treat erectile dysfunction.
- tolterodine used to treat overactive bladder
- colchicine used to treatment of gout
- calcium channel blockers verapamil, amlodipine, diltiazem) (used to treat high blood pressure)

St John's Wort (a herbal product used to treat depression)

- if you are taking oral contraceptive pills and diarrhoea or vomiting occurs, inform your doctor as you may need to take extra contraceptive precautions such as using a condom.
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat

or prevent malaria). Taking these medicines at the same time as clarithromycin may increase the chance of getting abnormal heart rhythms and other serious side effects that affect your heart.

- corticosteroids, given by mouth, by injection or inhaled (used to help suppress the body's immune system - this is useful in treating a wide range of conditions)

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interaction

KLARITHRAN with food, drink and alcohol

KLARITHRAN may be taken with or without meals and can be taken with milk.

Pregnancy, breast-feeding and fertility

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 this medicine.

Driving and using machines

It is not always possible to predict to what extent KLARITHRAN 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 KLARITHRAN affects them. KLARITHRAN may make you dizzy, confused or disorientated.

- **KLARITHRAN contains sucrose**

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

- **KLARITHRAN contains aspartame**

  This medicine contains 20 mg aspartame in each 5 ml suspension which is equivalent to 4 mg/ml. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

- **KLARITHRAN contains sodium**

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

3. HOW TO KLARITHRAN

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

Check with your doctor or pharmacist if you are not sure.

Children

Safety and efficacy in infants under 6 months of age has not been established. The recommended dose for children under 6 months is based upon a 7,5 mg/kg dose administered twice daily. See dosage table below.

The usual duration of treatment is 5 to 10 days, depending on the pathogen involved and the severity of infection.

In patients with severe renal function impairment (creatinine clearance <30 ml/min), the dosage of KLARITHRAN Should be reduced by half. Do not continue treatment in these patients for more than 14 days.

Weight	**Approximate age**	**Dose in ml of**	**Dose in ml of**

		125 mg/5 ml suspension	**250 mg/5 ml suspension**
8 to 11 kg	1 to 2 years	2,5 ml twice daily	-
12 to 19 kg	2 to 4 years	5 ml twice daily	2,5 ml twice daily
20 to 29 kg	4 to 8 years	7,5 ml twice daily	3,75 ml twice daily
30 to 40 kg	8 to 12 years	10 ml twice daily	5 ml twice daily

Reconstitution instructions:

The quantity of distilled water specified for the pack size in the table below should be added to the granules and the contents shaken well.

Pack size	**Volume of water to be added**
60 ml	34 ml
70 ml	40 ml
100 ml	55 ml

Adults: 250 mg twice daily.

In more severe infections, the dosage may be increased to 500 mg twice daily.

Renal impairment

Creatinine clearance (<30 ml/min): Reduce dose by half i.e. 250 mg once daily or 250 mg twice daily for severe infections. Limit the duration of treatment to 14 days

Eradication of *H. pylori*

Adults: 500 mg twice daily, in combination with an appropriate antibiotic and an acid lowering agent, for 7 to 10 days.

The safety and efficacy of **KLARITHRAN** in combination with proton-pump inhibitors other than omeprazole has not been established.

Atypical mycobacterial infections (MAC) in HIV patients

Adults: 500 mg twice daily

Treatment of disseminated MAC infections in AIDS patients should continue as long as clinical and microbiological benefit is demonstrated. A decrease in efficacy has been noted in patients taking **KLARITHRAN** for more than 12 weeks. **KLARITHRAN** should be used in conjunction with other antimycobacterial agents.

If you take more KLARITHRAN

If you take more KLARITHRAN than you should, you may experience an increase in side effects listed below (see **section 4**).

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 KLARITHRAN

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

If you stop taking KLARITHRAN

If you are unsure when to stop using KLARITHRAN**,** consult your doctor or pharmacist.

4. Possible side effects

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

If any of the following happens, stop taking KLARITHRAN 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,

- rash or itching,
- fainting,
- 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 KLARITHRAN. 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:

- changes in the way your heart beats for example if you notice it beating faster.
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).
- fits,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems,
- severe or prolonged diarrhoea, which may contain blood and/or mucus in it (this could be antibiotic associated colitis including pseudomembranous colitis). Diarrhoea may occur over two months after treatment with KLARITHRAN, in which case you should still contact your doctor.

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,
- irregular taste,
- nausea,
- vomiting,
- stomach pain,
- diarrhoea,
- indigestion,
- irregular liver function test,
- rash
- excessive sweating.

Less frequent side effects:

- thrush,
- inflammation of the stomach and intestines mild to severe nausea, vomiting, cramps and diarrhoea, usually caused by a bacteria or virus,
- infection,
- vaginal infection,
- if you are getting sick more often (colds), these may be signs of a decrease in your white blood cells (leukopenia),
- signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms or weakness, bruising, pale skin and/or breathlessness. This may be the result of a blood disorders (such as and neutropenia),
- coughing, wheezing, shortness of breath, a high temperature and a general ill feeling associated with an increase of white blood cells (eosinophilia),
- weight loss,
- lack of appetite,
- anxiety, nervousness,

- dizziness,
- sleepiness
- shaking,
- ringing in the ear or hearing loss,
- vertigo (balance disorder),
- changes in heart rhythm such as palpitations or an irregular heartbeat,
- nosebleed,
- inflammation of the lining of the oesophagus and lining of the stomach,
- pain, tenderness and swelling of the mouth and/or tongue,
- anal pain,
- bloating, constipation, dry mouth, burping, wind,
- situation where the bile (fluid made by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis),
- raised abnormal liver function blood test and raised blood tests,
- itching or itchy rash,
- muscle spasms or muscle pain,
- malaise, asthenia (weakness, lack of energy), chest pain, chills, fatigue.

Frequency not known:

- large, raised red patches on the skin, especially that of the face and legs, with fever and severe general illness which can sometimes recur and is caused by a bacterial infection (erysipelas)
- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding),
- psychotic disorders, confusion, depersonalization, depression, disorientation,
- seeing things (hallucinations),
- abnormal dreams or nightmares,
- mood of excitement, over activity and uninhibited behaviour,

- lack of taste, change in the sense of smell (parosmia), loss of smell,
- paraesthesia (numbness, tingling)
- deafness,
- type of heart rhythm disorder (torsade de pointes, ventricular tachycardia, ventricular fibrillation),
- bleeding,
- teeth or mouth discolouration,
- acute inflammation of the pancreas,
- acne
- myopathy (a muscle disease involving muscle strength reduction),
- 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),
- change in diagnostic test results (increased international normalized ratio [INR], prolonged prothrombin time,
- abnormal urine colour.

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

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of KLARITHRAN is important. It allows continued monitoring of the benefit/risk balance of KLARITHRAN. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

Suspected adverse reactions can also be reported directly to the Holder of Certificate of Registration via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000

5. HOW TO STORE KLARITHRAN

Store all medicines out of reach of children.

- Store at or below 25 ^{o}C.
- Keep the bottle tightly closed.
- Do not refrigerate or freeze.
- Store in the original package / container
- Discard the unused portion of constituted suspension after 14 days.
- Shake The Bottle Well Before Use.
- Protect from light / moisture
- Do not store in a bathroom
- Do not use medicine 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 KLARITHRAN 500 TABLETS contains

Each film-coated tablet contains clarithromycin 500 mg

Sugar free

Intragranular ingredients

Croscarmellose sodium, microcrystaliine cellulose, povidone,

purified water.

Extragranular ingredients

Colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, purified talc, stearic acid.

Film Coating Ingredients

Opadry 20H 52875(yellow), purified water.

What KLARITHRAN 125 mg/5 ml contains

The active substance is 125 mg Clarithromycin

Sucrose 2,929 g

Preservative: Sodium benzoate 0,2 % *m/v*

The other ingredients are:

Alginic acid, aspartame, carbomer (carbopol 974 P), colloidal anhydrous silica, croscarmellose sodium, flavour peppermint, flavour tutti frutti 051880 AP0551, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, Macrogol 1500 (polyethylene glycol), Methacrylic acid -ethyl acrylate copolymer (1:1) Dispersion 30%, Microcrystalline cellulose, monosodium citrate, purified water, sodium benzoate, sodium chloride, sucrose, titanium dioxide, talc, xanthan Gum

What KLARITHRAN 250 mg/5 ml contains

The active substance is 250 mg Clarithromycin

Sucrose 2,508 g

Preservative: Sodium benzoate 0,2 % *m/v*

The other ingredients are:

Alginic acid, aspartame, carbomer (carbopol 974 P), colloidal anhydrous silica, croscarmellose sodium, flavour peppermint, flavour tutti frutti 051880 AP0551, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, macrogol 1500 (polyethylene glycol), methacrylic acid -ethyl acrylate copolymer (1:1) Dispersion 30 %, microcrystalline cellulose, monosodium citrate, purified water, sodium benzoate, sodium chloride, sucrose, titanium dioxide, talc, xanthan gum

What KLARITHRAN looks like and contents of the pack

KLARITHRAN 500 TABLETS: Light yellow coloured, oval shaped, biconvex, film coated tablets with “C” and “2” debossed on either side of breakline on one side and notched on either sides along with the breakline.

KLARITHRAN 125 mg/5 ml: White to off-white granular powder forming a white to off-white suspension on constitution with water. The resulting suspension has a sweet taste and fruity flavour.

KLARITHRAN 250 mg/5 ml: White to off-white granular powder forming a white to off-white suspension on constitution with water. The resulting suspension has a sweet taste and fruity flavour.

KLARITHRAN 500 TABLETS: Blister strips comprising of clear PVC film (coated uniformly with PVdC on inner side) with a backing of aluminium foil (coated with heat seal lacquer) containing 10 or 14 tablets.

KLARITHRAN 125 mg/5 ml: Natural translucent HDPE bottle pack of

60 ml, 70 ml and 100 ml.

KLARITHRAN 250 mg/5 ml: Natural translucent HDPE bottle pack of

60 ml, 70 ml and 100 ml.

Holder of Certificate of Registration

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6 REGISTRATION NUMBER(S)

KLARITHRAN 500 TABLETS: 37/20.1.1/0437 (South Africa)

KLARITHRAN SUSPENSION 125 mg/5ml: 38/20.1.1/0174 (South Africa)

KLARITHRAN SUSPENSION 250 mg/5ml: 38/20.1.1/0175 (South Africa)

NS2	Klarithran 500 Tablets: 06/20.1.1/0058 (Namibia)
NS2	Klarithran Suspension 125 mg/5 ml: 06/20.1.1/0059 (Namibia)
NS2	Klarithran Suspension 250 mg/5 ml: 06/20.1.1/0060 (Namibia)

S2	Klarithran 500 Tablets: BOT 0500780 (Botswana)
S2	Klarithran Suspension 125 mg/5 ml: BOT 0801266 (Botswana)
S2	Klarithran Suspension 250 mg/5 ml: BOT 0801265 (Botswana)