1.5.5. Proposed Patient Information Leaflet

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 have previously had an allergic reaction to clarithromycin, other macrolides antibiotics such as erythromycin or azithromycin, or to any of the ingredients of **KLARITHRAN listed in section 6** (an allergic reaction may include rash, itching, swelling of the face, lips, hands/feet or breathing difficulties).
- If you are pregnant or intend to become pregnant.
- If you are currently breast-feeding.
- If you suffer severe dysfunction of the kidneys (you have creatinine clearance of less than 30 ml/min).
- If you are taking any of the following medicines: astemizole, cisapride, pimozide and terfenadine.

Warnings and precautions

Take special care with KLARITHRAN

- If you have sugar diabetes (there are reports of drop in blood sugar levels in patients taking insulin or oral hypoglycaemic drugs for treatment of diabetes).

Other medicines and KLARITHRAN

- ergot derivatives such as ergotamine tablets or inhalers (used for treatment of migraine)
- terfenadine or astemizole (used for treatment of allergies), cisapride (used for treatment of digestive problems), pimozide (used for treatment of mental illnesses).
- warfarin or other anticoagulants (blood thinning medicines).
- theophylline (an anti-asthma medicine).
- cyclosporin or tacrolimus (used following organ transplants).
- digoxin (used for treatment of heart failure).
- disopyramide or quinidine (used for treatment of certain abnormal heart rhythms).
- midazolam, alprazolam or triazolam (used as tranquilizers) phenytoin, valproic acid or carbamazepine (used for treatment of seizures).
- insulin or oral hypoglycaemic agents (used for treatment of diabetes).
- rifabutin (used for treatment certain infections).
- lovastatin or simvastatin (used for lowering elevated cholesterol levels).
- zidovudine (used for treatment of Human. Immunodeficiency Virus [HIV] infection).
- methylprednisolone (a medicine that suppresses the immune system).
- vinblastine (used in treatment of cancers).
- sildenafil (used for treatment of impotence in men).
- omeprazole (used for gastric ulcers).

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines).

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

The safety of this medicine for use during pregnancy and lactation has not been established.

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 health care provider for advice before taking this medicine.

Driving and using machines

Clarithromycin is not known to affect the ability to drive or use machines. However, make sure you know how to react to KLARITHRAN before you drive, use machines or engage in any other activity that could be dangerous if you are not alert.

- **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 125 mg/5 ml suspension**	**Dose in ml of 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 health care provider for advice.

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

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of the face, lips, tongue and hands/feet, fainting, high temperature.
- Severe skin reactions with blisters, sores or ulceration.

These are all very serious side effects. If you have them, you may have had a serious reaction to. You may need urgent medical attention or hospitalisation.

- Severe diarrhoea (which may contain blood or mucous) along with stomach cramps.
- Any irregular or fast heart beat
- Mental confusion
- Disorientation
- Ringing in the ears
- Convulsions
- Hallucinations
- Marked behaviour or mood changes
- Change in sense of reality
- Excessive anxiety
- Jaundice (yellowing of whites of eyes and skin), loss of appetite, pain in right upper abdomen, and general feeling of being unwell
- Unusual bleeding or increased tendency to bleed, persistent sore throat and frequent Infections

- Symptoms such as dizziness, palpitations, sweating, anxiety and sometimes fainting (these are manifestations of a drop in your blood sugar levels). (These are more likely if you are already receiving insulin or oral hypoglycaemic drugs for treatment of diabetes.

  These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Dizziness, headache, lack of sleep, bad dreams, nervousness.
- Nausea (feeling sick) or vomiting (being sick), abdominal pain, loose stools (diarrhoea), indigestion.
- Inflammation and discolouration of tongue, inflammation of the mouth, tooth discolouration (usually reversible with professional tooth cleaning).
- Impaired sense of taste
- Hearing loss
- White patches inside the mouth and/or on the tongue (oral thrush).

There may be changes in the results of certain laboratory tests:

- Abnormal liver function test.
- Increased creatinine levels in serum.

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 or 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 KLARITHRAN**.**

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.
- Discard the unused portion of constituted suspension after 14 days.
- Shake The Bottle Well Before Use.
- 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

Ranbaxy Pharmaceuticals (Pty) Ltd

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1724

South Africa

This leaflet was last revised in

19 October 2022

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)