Patient Information Leaflet

SCHEDULING STATUS

S4

KLARITHRAN MR 500 (TABLET)

Clarithromycin 500 mg

Contains sugar: Lactose monohydrate 127,80 mg per tablet

Read all of this leaflet carefully before you start taking KLARITHRAN MR 500

- 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 MR 500 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 MR 500 is and what it is used for
2. What you need to know before you take KLARITHRAN MR 500
3. How to take KLARITHRAN MR 500
4. Possible side effects
5. How to store KLARITHRAN MR 500
6. Contents of the pack and other information

1. What KLARITHRAN MR 500 is and what it is used for

KLARITHRAN MR 500 belong to broad and medium spectrum antibiotics.

KLARITHRAN MR 500 tablets 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 MR 500

Do not take KLARITHRAN MR 500:

- 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 MR 500 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 MR 500

- 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).
- If you have kidney and liver problems.

Other medicines and KLARITHRAN MR 500

- 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 MR 500 with food, drink and alcohol

KLARITHRAN MR 500 should be taken with food.

Swallow the tablets whole.

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

It is not always possible to predict to what extent KLARITHRAN MR 500 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 MR 500 affects them.

KLARITHRAN MR 500 contains lactose monohydrate

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

3. HOW TO KLARITHRAN MR 500

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

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

The usual recommended dose is one KLARITHRAN MR 500 tablet taken once daily with food.

In more severe infections your doctor may increase the dose to two KLARITHRAN MR 500 tablets taken once daily with food.

Swallow KLARITHRAN MR 500 tablets whole with a glass of water.

Take your tablets as directed and for as long as directed; do not stop them, even if you feel better.

If you have the impression that the effect of KLARITHRAN MR 500 is too strong or too weak, talk to your doctor or pharmacist.

If you take more KLARITHRAN MR 500

If you take more KLARITHRAN MR 500 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 MR 500

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 MR 500

If you are unsure when to stop using KLARITHRAN MR 500**,** consult your doctor or pharmacist.

4. Possible side effects

Not all side effects reported for KLARITHRAN MR 500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking KLARITHRAN MR 500, please consult your health care provider for advice.

If any of the following happens, stop taking / using KLARITHRAN MR 500 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 MR 500**.**

5. HOW TO STORE KLARITHRAN MR 500

Store all medicines out of reach of children.

- Store at or below 25 ^{o}C.
- Protect from 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 MR 500 contains

Each film-coated tablet contains clarithromycin 500 mg

Contains sugar: Lactose monohydrate 127,80 mg per tablet

The other ingredients are:

Intragranular ingredients

Colloidal anhydrous silica, Lactose monohydrate (Pharmatose), Hydroxypropyl methylcellulose (K15 MCR),

Microcrystalline cellulose, Povidone Ph. Eur. (PVP K30)

Extragranular ingredients

Colloidal anhydrous silica, Magnesium stearate, Purified water

Sodium stearyl fumarate

Film Coating Ingredients

Opadry 20 H 52875, Purified water

Imprinting Ingredients

Opacode S-1 -17823 Black, Isopropyl alcohol

What KLARITHRAN MR 500 looks like and contents of the pack

Pale yellow coloured, oval, biconvex, film coated tablets printed with 'CLNXL' in black ink on one side and plain on the other.

5 or 10 tablets packed in blister strips. Blister strips comprise of clear transparent PVC film coated with PVdC having a backing of plain aluminium foil.

Cartons contain 5 or 10 tablets.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1

Roodepoort

1724

South Africa

This leaflet was last revised in

23 August 2023

REGISTRATION NUMBER(S)

A39/20.1.1/0619 (South Africa)

S2 08/20.1.1/0087 (Namibia)

S2 BOT 0700981 (Botswana)