

1.3.2.1 Approved Patient Information Leaflet

SCHEDULING STATUS

S4

RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN 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.
- RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN MR 500 is and what it is used for
2. What you need to know before you take RAN-CLARITHROMYCIN MR 500
3. How to take RAN-CLARITHROMYCIN MR 500
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1. What RAN-CLARITHROMYCIN MR 500 is and what it is used for

RAN-CLARITHROMYCIN MR 500 is an antibiotic belonging to a group called the macrolides.

Antibiotics stop the growth of certain germs that cause infections. Its use is described below.

RAN-CLARITHROMYCIN MR 500 tablets are modified release tablets, which means that the active ingredient is released slowly from the tablet so that you only have to take the medicine once a day.

The RAN-CLARITHROMYCIN MR 500 tablets are used to treat infections such as:

1. Chest infections such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and soft tissue infections, which may also be called cellulitis, folliculitis or erysipelas.

RAN-CLARITHROMYCIN MR 500 Tablets are used in adults and children 12 years and older.

2. What you need to know before you take RAN-CLARITHROMYCIN MR 500

Do not take RAN-CLARITHROMYCIN MR 500:

- If you know that you are allergic to clarithromycin or other antibiotics from the same drug class (macrolide antibiotics) such as erythromycin or azithromycin, or if you are allergic to any of the other ingredients of this medicine (listed in section 6).
- If you are taking ergot alkaloids (e.g. ergotamine or dihydroergotamine tablets) or use ergotamine inhalers for migraine, or oral midazolam (for anxiety or to help sleep).
- If you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- If you are taking medicines called astemizole or terfenadine (medicine taken for hay fever or allergies), cisapride or domperidone (used for stomach disorders) or pimozide (medicine used to treat certain psychiatric diseases), as taking these medicines with RAN-CLARITHROMYCIN MR 500 tablets can cause serious disturbances in heart rhythm.

- If you are taking ticagrelor, ivabradine or ranolazine (medicine taken for angina or to reduce the chance of heart attack or stroke).
- If you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia).
- If you are taking drugs for high cholesterol (such as lovastatin or simvastatin).
- If you are taking a medicine containing lomitapide.
- If you have severe liver and/or severe kidney problems.
- If you had or currently have heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de points) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.
- If you are taking colchicine (for gout).
- 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 RAN-CLARITHROMYCIN MR 500).

Be sure to consult your doctor before taking clarithromycin if you think any of these conditions apply to you.

- If you are pregnant or breast feeding (see Pregnancy and breast-feeding).
- If you develop severe or prolonged diarrhoea during or after taking RAN-CLARITHROMYCIN MR 500 tablets, consult your doctor immediately.
- If you have certain heart problems (coronary artery disease, severe cardiac insufficiency, abnormal heart rhythms or clinically relevant slow heart rate).
- If you have impaired kidney function or impaired hepatic function as a dose reduction may be necessary.

- If you suffer from porphyria.
- 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 RAN-CLARITHROMYCIN MR 500').

Warnings and precautions

Take special care with RAN-CLARITHROMYCIN MR 500

- If you are pregnant or breast feeding (see Pregnancy and breast-feeding).
- If you develop severe or prolonged diarrhoea during or after taking RAN-CLARITHROMYCIN MR 500 tablets, consult your doctor immediately.
- If you have certain heart problems (coronary artery disease, severe cardiac insufficiency, abnormal heart rhythms or clinically relevant slow heart rate).
- If you have impaired kidney function or impaired hepatic function as a dose reduction may be necessary.

Other medicines and RAN-CLARITHROMYCIN MR 500

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

(This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, as your dose may need to be changed or you may need to have regular tests performed.

RAN-CLARITHROMYCIN MR 500 must not be taken with ergot alkaloids, astemizole, terfenadine, cisapride, domperidone, pimozide, ticagrelor, ranolazine, colchicine, some medicines for treating high cholesterol and medicines that are known to cause serious disturbances in heart rhythm (see under **Do not take RAN-CLARITHROMYCIN MR 500**).

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- digoxin, quinidine or disopyramide (heart drugs);
- warfarin, or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban, edoxaban (blood thinner);
- eletriptan (for migraine);
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy or bipolar disorder (manic-depression));
- St. John's Wort (a herbal product used to treat depression);
- theophylline (for asthma or emphysema);
- triazolam, alprazolam or intravenous or buccal (oromucosal) midazolam (for anxiety or to help sleep);
- omeprazole (for stomach disorders);
- quetiapine , cariprazine, aripiprazole or ziprasidone (for schizophrenia or other psychiatric conditions);
- zidovudine, ritonavir, atazanavir, saquinavir, nevirapine, efavirenz or etravirine (for HIV);
- rifabutin, rifapentine or rifampicine (antibiotics effective against some infections such as tuberculosis);
- itraconazole or fluconazole (for fungal infections);
- sildenafil, tadalafil or vardenafil (for erectile dysfunction);
- tolterodine (for bladder problems);
- methylprednisolone (a steroid to treat inflammation);
- ibrutinib or vinblastine (for cancer treatment);
- aprepitant (for preventing vomiting during chemotherapy);
- cilostazol (to improve circulation in the legs);
- any betalactam antibiotics (certain penicillins and cephalosporin antibiotics);

- tacrolimus, sirolimus or cyclosporin (to help organ transplants)□
- nateglinide, repaglinide, sulphonylureas or insulin (medicines used to treat diabetes);
- aminoglycosides (medicines used as antibiotics to treat infections);
- calcium channel blockers (medicines to treat high blood pressure);
- 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);

RAN-CLARITHROMYCIN MR 500 with food, drink and alcohol

RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN MR 500 affects them.

RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN MR 500 tablet taken once daily with food.

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

Swallow RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN MR 500 is too strong or too weak, talk to your doctor or pharmacist.

If you take more RAN-CLARITHROMYCIN MR 500

If you take more RAN-CLARITHROMYCIN MR 500 than you should, you may experience an increase in side effects listed below (see **section 4**).

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN MR 500

If you are unsure when to stop using RAN-CLARITHROMYCIN MR 500, consult your doctor or pharmacist.

4. Possible side effects

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

If any of the following happens, stop taking RAN-CLARITHROMYCIN MR 500 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to RAN-CLARITHROMYCIN MR 500. 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.
- Signs of recurrent infections, such as fever, chills or sore throat.
- Liver disease (causing unusual tiredness, nausea (feeling sick), vomiting (being sick), yellowing of skin or eyes).
- Fast or irregular heartbeats.
- Pseudomembranous colitis (abdominal or stomach cramps and pain, severe abdominal tenderness, severe watery or bloody diarrhoea, fever).
- Kidney failure (drowsiness, shortness of breath, fatigue, confusion, nausea (feeling sick), fits,

passing less urine than is normal for you).

- Liver diseases or liver failure (stomach pain, clay coloured stool, dark urine, unpleasant breath odour, unusual tiredness, nausea (feeling sick), vomiting (being sick) of blood, yellowing of skin or eyes).
- Interstitial nephritis (passing more or less urine than what is normal for you, blood in your urine, dark urine, nausea, vomiting).
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back).
- Bleeding or bruising more easily than normal.
- Red, blister forming rash with fever.
- Seizures (fits).
- Temporary paralysis or weakness of muscles.

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

Other side effects

Frequent side effects of RAN-CLARITHROMYCIN MR 500 are

- Change in results when testing your liver function.
- Difficulty sleeping.
- Distortion of the sense of taste.
- Diarrhoea, pain in the stomach area and stomach cramps.
- Nausea (feeling sick) and vomiting (being sick).
- Headache.
- Excessive sweating.

Less frequent side effects are:

- Vertigo (causing dizziness and nausea), hearing impairment or ringing in the ears.
- Changes in results when testing your blood enzymes and blood cell types, including decreased white blood cells, neutrophils and eosinophils.
- Candidiasis or vaginal infection (causing vaginal itching, redness or irritation and a burning sensation when urinating).
- Gastritis (pain, nausea, vomiting, vomiting blood, blood in the stool), gastroesophageal reflux disease (GORD), rectal pain, abdominal distension (causing belching, nausea and vomiting), constipation or flatulence.
- Mouth sores, a dry mouth or glossitis (causing swelling and pain of your tongue).
- Nosebleeds
- Change in results when testing your liver enzymes.
- Abnormal physical weakness or lack of energy.
- Chest pain.
- Anxiety, nervousness.
- Loss of appetite and losing weight.
- Low blood sugar levels.
- Feeling excessively tired, dizziness or tremors (involuntary trembling or shaking of hands and feet).
- Muscle spasms, muscle pain
- General feeling of being unwell, fever, weakness, fatigue and chills

The following are side effects with an unknown frequency:

- Low levels of white blood cells, increased number of certain white blood cells (agranulocytosis), decrease of the levels of blood platelets that help stop bleeding (thrombocytopenia)
- Psychotic disorder (causing anxiety, suspiciousness, depressed mood).

- Confusion, depersonalisation, depression, feeling disorientated or mania (causing racing thoughts, feeling energetic, talking fast and taking more risks).
- Hallucinations or having abnormal dreams.
- Haemorrhage (rupturing of a blood vessel).
- Erysipelas (causing a red, swollen and painful area of the skin, blisters and fever).
- Convulsions
- Loss of taste or loss or distortion of smell.
- Tingling or numbness of your hands and feet (pins and needles).
- Deafness.
- Easy or excessive bruising or bleeding and blood clotting slower than usual.
- Tongue or tooth discolouration.
- Abnormal urine colour.
- Acne.

If any of the following happens, stop taking / using RAN-CLARITHROMYCIN MR 500 and tell your doctor immediately or go to the casualty department at your nearest hospital:

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who.ums.org) found on SAHPRA website. Suspected adverse reactions can also be reported directly to the HCR via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000. By reporting side effects, you can help provide more information on the safety of RAN-CLARITHROMYCIN MR 500.

5. HOW TO STORE RAN-CLARITHROMYCIN MR 500

Store all medicines out of reach of children.

- Store at or below 25 °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 RAN-CLARITHROMYCIN 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 RAN-CLARITHROMYCIN 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

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