

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CLARITHROMYCIN UNIMED 500 mg Film-coated tablets

(Clarithromycin)

Sugar free

Read all of this leaflet carefully before you start taking CLARITHROMYCIN UNIMED 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.
- CLARITHROMYCIN UNIMED 500 has been prescribed for you, and you should not share the medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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1. What CLARITHROMYCIN UNIMED 500 is and what it is used for

CLARITHROMYCIN UNIMED 500 is an antibiotic which belongs to the group of macrolide antibiotics. It stops the growth of certain bacteria which cause infections.

CLARITHROMYCIN UNIMED 500 is used to treat:

1. Chest infections, such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and soft tissue infections
4. *Helicobacter pylori* infections associated with duodenal ulcers, in combination with other antibacterials and appropriate ulcer healing agents.

2. What you need to know before you take KLARINOVA

Do not take CLARITHROMYCIN UNIMED 500:

- if you are allergic to clarithromycin, other macrolide antibiotics (such as erythromycin or azithromycin) or to any of the other ingredients of this medicine. (listed in **section 6**).
- if you or someone in your family has a history of certain abnormal heart rhythms (ventricular arrhythmia, ventricular fibrillation including torsade's de pointes) or
- changes in the heart activity as measured in the electro-cardiogram called "QT prolongation".
- if your blood potassium is low (hypokalaemia).
- if you suffer from severe liver failure and kidney problems at the same time
- if you are taking
 - ergotamine, dihydroergotamine (medicines to treat migraine)
 - oral midazolam (a sedative)
 - terfenadine or astemizole (antiallergics)
 - cisapride (gastric medicine)
 - domperidone (gastric medicine)
 - pimozide, quetiapine, cariprazine, and aripiprazole (antipsychotic)
 - ticagrelor (to prevent blood clotting)

- ranolazine (to treat angina pectoris)
- lovastatin, simvastatin (medicines to lower cholesterol)
- colchicine (to treat gout).
- other medicines which are known to cause serious disturbances in heart rhythm

Warnings and precautions

Take special care with CLARITHROMYCIN UNIMED 500

- If you have reduced liver or kidney function. If you develop symptoms such as anorexia, jaundice, dark urine, itchy skin, or tender abdomen, decreased urine, contact your doctor.
- If you develop severe or prolonged diarrhoea (pseudomembranous colitis) during or after taking CLARITHROMYCIN UNIMED 500, consult your doctor immediately. Inflammation of the colon (pseudomembranous colitis) has been reported with nearly all antibacterial medicines including CLARITHROMYCIN UNIMED 500.
- If you develop severe hypersensitivity reactions such as rash, swelling of the face, lips, tongue or throat. Stop taking CLARITHROMYCIN UNIMED 500 and contact your doctor immediately
- If you currently 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).
- your potassium level is low
- your magnesium level has previously been low
- If you have used clarithromycin before on several occasions or for a long time as you may get other infections.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking CLARITHROMYCIN UNIMED 500.

Other medicines and CLARITHROMYCIN UNIMED 500

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Certain other medicines may affect the effectiveness of CLARITHROMYCIN UNIMED 500 or vice-versa. Taking CLARITHROMYCIN UNIMED 500 with certain medicines may also increase the severity of adverse reactions.

Such medicines include:

- Astemizole, terfenadine (antiallergic), pimozide (antipsychotic), cisapride (gastric medicine), domperidone (gastric medicine), ergotamine, dihydroergotamine (migraine medicines), lovastatin, simvastatin (medicines to lower cholesterol), ticagrelor (to prevent blood clotting), ranolazine (used to treat angina pectoris), colchicine (to treat gout), oral midazolam
- Alprazolam, triazolam, intravenous or oromucosal midazolam (hypnotics)
- Digoxin (heart medicine)
- Verapamil, amlodipine, diltiazem (medicines for high blood pressure)
- Quinidine or disopyramide (heart medicines)
- Theophylline (antiasthmatic)
- Atorvastatin, rosuvastatin (cholesterol lowering agents)
- Insulin and other medicines for the treatment of diabetes (such as nateglinide or repaglinide or sulphonylureas gliclazide or glimepiride used in the treatment of type II diabetes)
- Omeprazole (gastric medicine)
- Sildenafil, tadalafil, vardenafil [medicines to treat erectile dysfunction or for use in pulmonary arterial hypertension {high blood pressure in the blood vessels of the lung}]
- Tolterodine (to treat overactive bladder syndrome)
- Warfarin (blood thinning medicine)
- Cilostazol (used to improve circulation in the legs)
- Ciclosporin, sirolimus, tacrolimus (immunosuppressants)
- Methylprednisolone (a corticosteroid)
- Vinblastine (medicine for cancer therapy)
- Carbamazepine, phenytoin, valproate (medicines to treat epilepsy)
- Ibrutinib (medicine for cancer therapy)
- Quetiapine, cariprazine, aripiprazole or other antipsychotic medicines.

- Ritonavir (antiviral) and fluconazole (medicine to treat fungal infections) may increase the effect of CLARITHROMYCIN UNIMED 500.
- CLARITHROMYCIN UNIMED 500 may weaken the effect of zidovudine (antiviral). In order to avoid this, you should leave a 4-hour interval between taking these medicines.

Both, the effect of CLARITHROMYCIN UNIMED 500 and the effect of the following medicines may be increased when taken together:

- Atazanavir, saquinavir (medicines to treat HIV)
- Itraconazole (medicine to treat fungal infections)

The following medicines may weaken the effect of CLARITHROMYCIN UNIMED 500:

- Rifampicin, rifabutin, rifapentine (antibiotics used in the treatment of certain bacterial infections)
- Efavirenz, etravirine, nevirapine (anti-viral drugs used in the treatment of HIV)
- Phenytoin, carbamazepine, phenobarbitone (antiepileptic)
- St John's Wort (a herbal product used to treat depression)

Tell your doctor if you are taking oral contraceptive pills and diarrhoea, vomiting or breakthrough bleeding occurs, as you may need to take extra contraceptive precautions such as using a condom.

Taking CLARITHROMYCIN UNIMED 500 with food and drink

CLARITHROMYCIN UNIMED 500 can be taken before, with or after food.

Pregnancy, breast-feeding and fertility

CLARITHROMYCIN UNIMED 500 is not usually recommended for use during pregnancy and breastfeeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

CLARITHROMYCIN UNIMED 500 has generally no effect on the ability to drive or use machines but may cause side effects such as dizziness, confusion and disorientation. Do not drive or use machines unless you are sure you are not affected.

3. How to take CLARITHROMYCIN UNIMED 500

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

Always take CLARITHROMYCIN UNIMED 500 exactly as your doctor or pharmacist has told you.

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

The dose your doctor prescribes depends on the type of infection and how bad the infection is. It also depends on how your kidneys are working.

For chest infections, throat or sinus infections and skin and soft tissue infections

The dose of CLARITHROMYCIN UNIMED 500 for adults and children over 12 years is one 500 mg tablet twice daily.

For the treatment of *Helicobacter pylori* infection associated with duodenal ulcers

CLARITHROMYCIN UNIMED 500 mg twice daily in combination with amoxicillin 1000 mg twice daily and omeprazole 20 mg daily for 7 - 10 days.

The treatment combination that you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you.

Your doctor will tell you how long your treatment with CLARITHROMYCIN UNIMED 500 will last. If you have the impression that the effect of CLARITHROMYCIN UNIMED 500 is too strong or too weak, tell your doctor or pharmacist.

- Take this medicine by mouth.

- Swallow the tablets whole with a drink of water.
- Take CLARITHROMYCIN UNIMED 500 according to instructions from your doctor or pharmacist measures.

If you take more CLARITHROMYCIN UNIMED 500 than you should

If you have taken too many CLARITHROMYCIN UNIMED 500 tablets, or if someone else has taken your CLARITHROMYCIN UNIMED 500 tablets, seek medical advice urgently. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. An overdose of CLARITHROMYCIN UNIMED 500 is likely to cause vomiting and stomach pains.

If you forget to take CLARITHROMYCIN UNIMED 500

- If you forget to take a dose, take it as soon as you remember.
- Do not take a double dose to make up for forgotten individual doses.

If you stop taking CLARITHROMYCIN UNIMED 500

Do not stop taking CLARITHROMYCIN UNIMED 500 tablets before the end of the course, even if you think the infection is better. Stopping early can mean that the infection quickly comes back. If you are not sure about anything, ask your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

CLARITHROMYCIN UNIMED 500 can have side effects.

Not all side effects reported for CLARITHROMYCIN UNIMED 500 are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking CLARITHROMYCIN UNIMED 500, please consult your health care provider for advice.

Serious side effects

If any of the following happens, stop taking this medicine immediately. You may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the casualty department at your nearest hospital.

- fever, sore throat or mouth ulcers due to infection (signs of low levels of white blood cells)
- rash, itching, hives, breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, low blood pressure (hypotension), with or without mild generalized itching, skin reddening, facial/throat swelling, blue discoloration of the lips, tongue or skin. This is a sign that you may have developed an allergic reaction.
- irregular heartbeat (change in the electrical activity of the heart)
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These are signs that your liver may have inflammation and not be working properly.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe or prolonged diarrhoea, which may have blood or mucus in it (signs of inflammation of the colon). Diarrhoea may occur over two months after treatment with CLARITHROMYCIN UNIMED 500, in which case you should still contact your doctor.
- high or low urine output, drowsiness, confusion, and nausea caused by kidney inflammation
- 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).
- unusual bruising or bleeding caused by low blood platelets
- severe bleeding
- muscle pain or weakness known as rhabdomyolysis (a condition which causes the breakdown of muscle tissue which can result in kidney damage).

- severely decreased urine output
- rare allergic skin reactions which cause severe illness with ulceration of the mouth, lips and skin with rash, fever and inflammation of internal organs (DRESS).
- a red, scaly rash with bumps under the skin and blisters (symptoms of exanthematous pustulosis).

Other possible side effects

Tell your doctor if any of the following side effects bother you:

Frequent

- difficulty falling asleep
- changes in the senses of taste (for example metallic or bitter taste)
- headache
- abdominal pain, feeling or being sick, diarrhoea, indigestion, heart burn
- rash

Less frequent

- oral or vaginal 'thrush' (a fungal infection)
- loss or reduction of appetite
- anxiety
- dizziness, tremor
- impaired hearing
- spinning sensation (vertigo)
- ringing in the ears (tinnitus)
- chest pain or changes in heart rhythm such as palpitations or an irregular heartbeat
- increase of liver enzymes in the blood
- swelling, redness or itchiness of the skin

- inflammation of the skin characterized by the presence of the bullae which are filled with fluid, itchy and painful rash

Frequency not known (frequency cannot be estimated from the available data):

- inflammation of the colon
- certain bacterial infections of the skin and underlying tissues (erysipelas)
- decrease in white blood cells (leukopenia)
- 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)
- 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)
- nightmares, confusion, disorientation, hallucinations (seeing things that are not there), psychosis (loss of contact with reality), a feeling of loss of identity, depression nightmares and mania (feeling of elation or over-excitement)
- convulsion (fits)
- paraesthesia, more commonly known as 'pins and needles'
- loss of taste or smell or inability to smell properly
- deafness
- type of heart rhythm disorder (Torsade de pointes, ventricular tachycardia)
- inflammation of the stomach and intestines
- inflammation of the pancreas
- tongue discolouration, tooth discoloration
- situation where the bile (fluid made by the liver and stored in the gallbladder) cannot flow from the gallbladder to the duodenum (cholestasis)
- inflammation of the liver
- muscle spasms, muscle pain or loss of muscle tissue

- loss of blood (haemorrhage)
- abnormal blood test results - prolonged blood clotting time
- urine colour abnormal

CLARITHROMYCIN UNIMED 500 may also affect some laboratory tests such as causing raised abnormal kidney and liver function blood test and raised blood tests. If you have to go to hospital for a blood test it is important that you tell the doctor or nurse that you are taking CLARITHROMYCIN UNIMED 500.

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. 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 CLARITHROMYCIN UNIMED 500.

5. How to store CLARITHROMYCIN UNIMED 500

Store all medicines out of reach of children.

Store at or below 25 °C.

This medicinal product does not require any special storage conditions.

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 CLARITHROMYCIN UNIMED 500 contains

Each film-coated tablet contains 500 mg of clarithromycin

The other ingredients are cellulose microcrystalline, croscarmellose sodium, povidone, colloidal anhydrous silica, magnesium stearate, purified water, hypromellose, propylene glycol, titanium dioxide, hydroxypropyl cellulose, vanillin, sorbic acid, iron oxide yellow

What CLARITHROMYCIN UNIMED 500 looks like and contents of the pack

CLARITHROMYCIN UNIMED 500 tablets are light yellow coloured, oval shaped, biconvex film-coated tablets, with D debossed on one side and 63 on the other side.

They are available in blister packs of 10 tablets.

Holder of Certificate of Registration

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