

Applicant: Unimed Healthcare (Pty) Ltd

Product Names: KLARYVID 250
KLARYVID 500

Dosage form and strengths: Each film-coated tablet contains Clarithromycin 250 mg
Each film-coated tablet contains Clarithromycin 500 mg

Patient Information Leaflet (PIL)

KLARYVID 250 (film-coated tablets)

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SCHEDULING STATUS S4

KLARYVID 250 (film-coated tablets)

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Clarithromycin

Contains a preservative: Sorbic Acid 0,063 % w/w

Sugar free

Read all of this leaflet carefully before you start taking KLARYVID

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- KLARYVID 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 this leaflet

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

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1. What KLARYVID is and what it is used for

KLARYVID contains clarithromycin, an antibiotic of the macrolide group which is used for the treatment of various infections such as:

- chest infections (like pneumonia and bronchitis),
- infections of the middle ear,
- skin and soft tissue infections,
- infections of the throat and sinuses.

KLARYVID in combination with another antibiotic e.g. amoxicillin and a specific medicine indicated to reduce stomach acid, can also be used for the treatment of a duodenal ulcer when this ulcer is caused by a bacteria, *Helicobacter pylori*.

Your doctor will tell you what you are being treated for.

2. What you need to know before you take KLARYVID

Do not take KLARYVID

- If you are hypersensitive (allergic) to clarithromycin or other macrolide antibiotics (erythromycin or azithromycin) or any of the other ingredients of KLARYVID (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).

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- If you are taking astemizole or terfenadine (medicines used to treat allergies), cisapride or domperidone (a medicine used to treat gastrointestinal tract disorders), pimozone (a medicine used to treat mental disorders), because they may cause serious disturbances in heart rhythm when taken together with KLARYVID.
- 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 blood clotting) or ranolazine (a cardiac medicine).
- If you are taking lovastatin or simvastatin (statin medicines used to lower blood cholesterol) as the combination with KLARYVID 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 (antipsychotic medicines).
- 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 KLARYVID

- 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 KLARYVID in your blood. Co-administration has been reported to cause a higher

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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 breathe better.
- If you develop severe or prolonged diarrhoea (pseudomembranous colitis), which may have blood or mucus in it, during or after taking KLARYVID, 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) used 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 in 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, KLARYVID 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).

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

Other medicines with KLARYVID

Always tell your healthcare professional if you are taking any other medicine.

(This includes 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 **KLARYVID**:

- 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

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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 or apixaban 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



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- 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.

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

Pregnancy and breastfeeding

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 KLARYVID 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 KLARYVID affects them. KLARYVID may make you dizzy, confused or disorientated.

KLARYVID contains sodium

KLARYVID 250 and KLARYVID 500 contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take KLARYVID

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

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Always take KLARYVID exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine may be taken with food or milk or on an empty stomach.

Your doctor or healthcare professional will know and tell you the correct dosage for KLARYVID tablets. It also depends on how your kidneys are working.

KLARYVID is not suitable for use in children under the age of 12 years.

For mild to moderate infections, the usual dose in adults and children over 12 years of age is 250 mg twice daily.

For more severe infections, 500 mg twice daily.

For peptic ulcer caused by the bacteria *Helicobacter pylori* (in combination with an appropriate antibiotic e.g. amoxicillin and a medicine that specifically reduces stomach acid): 500 mg twice daily for 7 to 10 days.

Prevention of infections in AIDS patients with very low CD4 cells, Clarithromycin 500 mg twice daily.

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

If you take more KLARYVID than you should

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

If you forget to take KLARYVID

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

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

If any of the following happens, stop taking KLARYVID 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).



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These are all very serious side effects. If you have them, you may have had a serious reaction to KLARYVID. 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 KLARYVID, 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,

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- 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,

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- 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,



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- 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 tell 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 KLARYVID.

5. How to store KLARYVID

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Store at or below 25 °C and protect from light.

Keep the blisters in the carton until required for use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton.

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 KLARYVID contains:

- The active substance in KLARYVID is clarithromycin.
Each KLARYVID 250 tablet contains clarithromycin 250 mg.
Each KLARYVID 500 tablet contains clarithromycin 500 mg.
- The other ingredients are colloidal anhydrous silica, microcrystalline cellulose, croscarmellose sodium, povidone, stearic acid, talc, magnesium stearate, tablet coating consisting of hydroxypropylmethyl cellulose, propylene glycol, sorbitan monooleate, vanilla dry flavour, quinoline yellow lake (E104), titanium dioxide (E171), hydroxypropyl cellulose and sorbic acid as a preservative (0,063 % w/w).

What KLARYVID looks like and contents of the pack

KLARYVID 250: Yellow, film coated, oval-shaped, convex tablets, scored on one side- (14,5 mm).

KLARYVID 500: Yellow, film coated, oval-shaped, convex tablets, scored on one side- (19,0 mm).

KLARYVID 250 tablets are supplied in PVC/PVDC/Aluminium blister packs containing 10 tablets, packed into an outer carton together with a package insert.

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KLARYVID 500 tablets are supplied in PVC/PVDC/Aluminium blister packs containing 10 and 14 tablets, packed into an outer carton together with a package insert.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

Corner Birch Road & Bluegum Avenue

Anchorville

Lenasia, 1827

South Africa

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