

KLAR 250 & KLAR 500

Clarithromycin Tablets 250 mg & Clarithromycin Tablets 500 mg

Consumer Medication Information Leaflet (RiMUP)

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What is KLAR tablets used for

KLAR tablets are indicated for the treatment of the following bacterial infections.

- Treatment of infections caused by pathogens sensitive to Clarithromycin.
- Infection of nose-pharynx tract (tonsillitis, pharyngitis) and of paranasal sinuses. Infections of lower respiratory tract: bronchitis (inflammation of airways in the lungs), bacterial pneumonia and atypical pneumonia.
- Skin infections: impetigo, erysipelas (bacterial infection in the upper layer of the skin), folliculitis (inflammation of hair follicles), furunculosis (infection of hair follicles) and septic wounds.
- Eradication of *H.pylori* in patients with duodenal ulcers in the presence of acid suppression effected by omeprazole.

How KLAR tablets works

KLAR belongs to a group of medicine called macrolide antibiotics. Antibiotics stop the growth of bacteria which cause infections.

Before you use KLAR tablets

-When you must not use it

- If you are allergic to clarithromycin, other macrolide antibiotics or any of the other ingredients of this medicine.

- If you have a history of certain abnormal heart rhythms (ventricular arrhythmia, including torsades de pointes) or changes in the heart activity as measured in the electrocardiogram called "QT prolongation"
- If you suffer from severe liver failure and kidney problems at the same time.
- If you have low levels of potassium in the blood (a condition known as hypokalaemia).
- If you are taking any of the following medicines:
 - other macrolides (eg erythromycin, azithromycin)
 - ergotamine, dihydroergotamine (medicines to treat migraine)
 - astemizole, terfenadine (used for allergies)
 - cisapride (gastric medicine)
 - pimozide (antipsychotic)
 - lovastatin, simvastatin (medicines to lower cholesterol)
 - colchicines (medicine to treat gout),
 - ticagrelor or ranolazine (medicines to prevent stroke or heart attack).

Pregnancy and lactation

Do not take KLAR tablets if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take KLAR tablets if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Do not take KLAR if you are taking any of the following medicines: domperidone (used for nausea & vomiting).

Take special care with KLAR tablets;

- If you are pregnant, particularly during the first three months of pregnancy.
- If you have any kidney problems.
- If you have any liver problems or have been taking other medicine toxic to the liver. You have to stop treatment and contact your doctor if signs and symptoms of liver disease develop, such as anorexia (an eating disorder characterized by low weight,

fear of gaining weight, and a strong desire to be thin, resulting in food restriction), jaundice (yellowing of the skin and white of the eyes), dark urine, pruritus (itching) or tender abdomen.

- If you have known hypersensitivity to penicillin (an antibiotic).
- If you had diarrhoea following antibiotic use.
- If you are taking colchicine (a medicine to treat gout).
- If you are taking triazolobenzodiazepines (a group of sedatives such as triazolam, midazolam).
- If you are taking other drugs that are toxic to the ears (especially aminoglycosides, a group of antibiotic).
- If you have any heart problem or taking medicines that are associated with QT-prolongation (a heart rhythm disorder), such as astemizole, cisapride, pimozide and terfenadine.
- If you have hypomagnesaemia (low level of magnesium in the blood) or hypokalemia (low level of potassium in the blood).
- If you are prescribed clarithromycin for pneumonia, skin and soft tissue infections, sensitivity test may be performed.
- If you have severe acute hypersensitivity reactions such as anaphylaxis (fatal allergic reaction), Stevens-Johnson Syndrome or toxic epidermal necrolysis (immune disorder of the skin), clarithromycin therapy should be discontinued immediately and appropriate treatment should be urgently initiated.
- If you are taking medicines to lower cholesterol (Statins such as lovastatin or simvastatin).
- If you are taking medicines to lower blood glucose (eg sulphonylurea, insulin). Careful monitoring of blood glucose is recommended.
- If you are taking warfarin (an oral anticoagulant). Frequent monitoring is required.
- If you are taking clarithromycin for pharyngitis (inflammation of the back of the throat) due to Streptococcal infection (a bacterial infection),

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treatment duration should be at least 10 days.

- If you are taking clarithromycin for *H.pylori*.

If any of these apply to you, consult your doctor before taking KLAR tablets.

-Taking other medications

You should not take KLAR tablets if you are taking any of the medicines listed below.

Tell your doctor if you are taking any of the following medicines as your dose may need to be changed or you may need to have regular tests performed:

- cisapride (for gastrointestinal disorder), pimozide (for psychotic disorder), astemizole (for allergy) or terfenadine (for allergy)
- ergotamine or dihydroergotamine (medicines to treat migraine)
- lovastatin or simvastatin (medicines to lower cholesterol)
- quetiapine (antipsychotic)
- digoxin, quinidine or disopyramide (for heart problems)
- nateglinide or repaglinide (used to lower blood glucose levels)
- omeprazole (for treatment of indigestion and gastric ulcers) unless your doctor has prescribed it for you to treat *Helicobacter pylori* infection associated with duodenal ulcer
- sildenafil, vardenafil and tadalafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- theophylline (used in patients with breathing difficulties such as asthma)
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy)
- tolterodine (for overactive bladder)
- triazolam, alprazolam or midazolam (sedatives)
- etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (anti-viral drugs)
- rifabutin, rifampicin, rifapentine (used in the treatment of tuberculosis)

- fluconazole, itraconazole (an antifungal)
- aminoglycosides (a class of antibiotic)
- colchicine (usually taken for gout)
- verapamil, amlodipine, diltiazem (for lowering of blood pressure)
- warfarin (for thinning the blood)
- cilostazol (for poor circulation)
- methylprednisolone (a corticosteroid)
- vinblastine (for treatment of cancer)
- ciclosporin, sirolimus and tacrolimus (immunosuppressants)
- St John's Wort (a herbal product used to treat depression)

How to use KLAR tablets

-How much to use

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

In adults the usual recommended dosage of Clarithromycin in adults and children 12 years of age or older, is one 250mg tablet twice daily. In more severe infections, the dosage can be increased to 500mg twice daily.

The usual duration of therapy is 5 to 14 days, excluding treatment of community acquired pneumonia and sinusitis which require 6 to 14 days of therapy.

Eradication of *H.pylori* in patients with duodenal ulcers Adults: The usual dose of Clarithromycin is 500 mg three times daily for 14 days.

Dual therapy: Clarithromycin should be administered with oral omeprazole 40 mg once daily. The pivotal study was conducted with omeprazole 40 mg once daily for 28 days. Supportive studies have been conducted with omeprazole 40 mg once daily for 14 days.

Triple Therapy: Clarithromycin 500 mg twice daily should be

given with amoxicillin 1000 mg twice daily and omeprazole 20 mg daily for 10 days.

Elderly: As for adults.

Pediatric: The use of Clarithromycin IR has not been studied in children less than 12 years of age.

Renal impairment: In patients with renal impairment with creatinine clearance less than 30 mL/min, the dosage of clarithromycin should be reduced by one-half, i.e., 250 mg once daily or 250 mg twice daily in more severe infections.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking KLAR tablets for as long as your doctor recommends.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Taking too much clarithromycin can cause gastro-intestinal symptoms, altered mental status, paranoid behaviours, hypokalaemia (low potassium level in blood) and hypoxemia (low level of oxygen in blood).

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking KLAR tablets.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give KLAR tablets to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, KLAR tablets can cause side effects although not everybody gets them.

- Infections and infestations:

Oral moniliasis (yeast infection of the mouth and throat)

- Psychiatric disorders:

Insomnia

-Nervous system disorders:

Dysgeusia (distortion of the sense of taste), headache, taste perversion

- Gastrointestinal disorders:

Diarrhoea, vomiting, abdominal pain, nausea, dyspepsia

-Hepato-biliary disorders:

Liver function test abnormal

- Skin and subcutaneous tissue disorders:

Rash, hyperhidrosis (excessive sweating)

KLAR may cause severe allergy and serious skin reactions.

Stop using KLAR and seek medical assistance immediately if you experience any of the following symptoms:

- Skin reddening, blisters, rash, fever, sore throat or eye irritation

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of KLAR tablets

-Storage

Keep this medicine out of the sight and reach of children.

Keep these tablets in a dry, safe place. Store below 30 °C. Protected from light.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

KLAR 250 is Light yellow coloured, oval shaped, biconvex film - coated tablets, with 'D' debossed on one side and '62' on the other side.

KLAR 500 is Light yellow coloured, oval shaped, biconvex film - coated tablets, with 'D' debossed on one side and '63' on the other side.

-Ingredients

- Active ingredient(s):
Clarithromycin
- Inactive ingredient(s):
Microcrystalline cellulose, croscarmellose sodium, silica, colloidal anhydrous, magnesium stearate, povidone, hypromellose, propylene glycol, titanium dioxide (E 171), hydroxypropyl cellulose, vanillin, sorbic acid and iron oxide yellow (E 172).

-MAL number

KLAR 250: MAL18046160AZ

KLAR 500: MAL18046161AZ

Manufacturer

Aurobindo Pharma Limited

Unit III, Survey No 313, 314, Bachupally, Bachupally Mandal, Medchal Malkajgiri District, Hyderabad, 500090, India

Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd

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Date of revision

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