

Clarithromycin Oral

CLARITHROMYCIN - ORAL

IMPORTANT NOTE: This is a summary and does not contain all possible information about this product. For complete information about this product or your specific health needs, ask your health care professional. Always seek the advice of your health care professional if you have any questions about this product or your medical condition. This information is not intended as individual medical advice and does not substitute for the knowledge and judgment of your health care professional. This information does not contain any assurances that this product is safe, effective, or appropriate for you.

CLARITHROMYCIN - ORAL

(kla-RITH-row-MYE-sin) COMMON BRAND NAME(S): Biaxin

USES:

Clarithromycin is used to treat a wide variety of bacterial infections. This medication can also be used in combination with anti-ulcer medications to treat certain types of stomach ulcers. It may also be used to prevent certain bacterial infections. Clarithromycin is a macrolide antibiotic that works by stopping the growth of bacteria.

This antibiotic treats only bacterial infections. It will not work for viral infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

HOW TO USE:

Take this medication by mouth with or without food, usually twice daily or as directed by your doctor. If stomach upset occurs, you may take it with food or milk.

Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at evenly spaced intervals, at the same time(s) each day. The dosage and duration of therapy is based on your medical condition and response to therapy.

If you are using this medication to treat an infection, continue to take this medication until the full-prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a relapse of the infection. Inform your doctor if your condition persists or worsens.

If you are taking this medication for the prevention of certain bacterial infections, take it exactly as directed by your doctor. Do not stop taking the medication without your doctor's approval.

SIDE EFFECTS:

Diarrhea, nausea, vomiting, stomach upset, changes in taste, and headache may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: hearing loss, mental/mood changes.

Seek immediate medical attention if any of these rare but very serious side effects occur: severe dizziness, fainting, fast/irregular heartbeat.

Tell your doctor immediately if any of these rare but very serious side effects occur: new signs of infection (e.g., fever, persistent sore throat), muscle weakness, persistent nausea/vomiting, severe stomach/abdominal pain, dark urine, yellowing of eyes or skin, change in the amount of urine.

This medication may rarely cause a severe intestinal condition (pseudomembranous colitis) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have any of the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool.

Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection (oral or vaginal fungal infection). Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge or other new symptoms.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

PRECAUTIONS:

Before taking clarithromycin, tell your doctor or pharmacist if you are allergic to it; or to other macrolide antibiotics (e.g., erythromycin, azithromycin); or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver or kidney disease, a certain type of muscle disease (myasthenia gravis).

Clarithromycin may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can infrequently result in serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that require immediate medical

attention. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may affect the heart rhythm (see also Drug Interactions section). Before using clarithromycin, tell your doctor or pharmacist if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death).

Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using clarithromycin safely.

This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.

Based on information for similar drugs, this medication may pass into breast milk. Therefore, consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first.

This drug should not be used with the following medications because very serious interactions may occur: eletriptan, eplerenone, ergot alkaloids (e.g., ergotamine, dihydroergotamine), ivabradine, quinupristin-dalfopristin, ranolazine.

If you are currently using any of these medications, tell your doctor or pharmacist before starting clarithromycin.

Many drugs besides clarithromycin may affect the heart rhythm (QT prolongation), including amiodarone, dofetilide, quinidine, sotalol, pimozide, procainamide, moxifloxacin, gatifloxacin, propafenone, thioridazine, macrolide antibiotics (such as erythromycin), among others. Therefore, before using clarithromycin, report all medications you are currently using to your doctor or pharmacist.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: drugs affecting liver enzymes that remove clarithromycin from your body (such as rifamycins - including rifabutin and rifampin, and azole antifungals - including itraconazole and fluconazole), certain HIV medications (e.g., zidovudine, delavirdine, protease inhibitors such as atazanavir, ritonavir), certain anti-seizure medications (e.g., carbamazepine, phenytoin, valproate), "blood thinners" (e.g., warfarin), colchicine, digoxin, live bacterial vaccines.

This drug can slow down the removal of other drugs from your body by affecting certain liver enzymes. Some examples of these affected drugs include alfentanil, certain benzodiazepines (e.g., alprazolam, midazolam, triazolam), bromocriptine, cilostazol, corticosteroids (e.g., methylprednisolone), cyclosporine, disopyramide, fentanyl, repaglinide, sildenafil, certain statins (atorvastatin, lovastatin, simvastatin), tacrolimus, tolterodine, theophylline.

This medication may decrease the effectiveness of combination-type birth control pills. This can result in pregnancy. You may need to use an additional form of reliable birth

control while using this medication. Consult your doctor or pharmacist for details. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE:

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222.

NOTES:

Do not share this medication with others.

This medication has been prescribed for your current condition only. Do not use it later for another infection unless told to do so by your doctor. A different medication may be necessary in those cases.

Laboratory and/or medical tests (e.g., blood counts, cultures, liver or kidney function tests) may be performed periodically to monitor your progress or check for side effects.

Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at controlled room temperature away from light and moisture. Consult your pharmacist for the specific temperature range for your product. Do not store in the bathroom. Keep all medicines away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

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