

KLASH -(Clarithromycin Tablets, USP)

DESCRIPTION: Clarithromycin is a semi-synthetic macrolide antibiotic. Chemically it is 6-O-methylerythromycin. The molecular formula is C₃₈H₆₉NO₁₃, and the molecular weight is 747.96.

Ingredient(s): Each KLASH 250 mg Tablet contains: Clarithromycin USP 250mg.
Each KLASH 500 mg Tablet contains: Clarithromycin USP 500mg.

Indications: KLASH is indicated for treatment of infection due to susceptible organisms, such infections include:

- Lower respiratory tract infections (e.g., bronchitis, pneumonia);
- Upper respiratory tract infections (e.g., pharyngitis, sinusitis);
- Skin and soft tissue infections (e.g., folliculitis, erysipelas);
- Disseminated or localized mycobacterial infections due to *Mycobacterium avium* or *Mycobacterium intracellulare*. Localized infections due to *Mycobacterium chelonae*, *Mycobacterium fortuitum*, or *Mycobacterium kansasii*;
- Clarithromycin is indicated for the prevention of disseminated *Mycobacterium avium* complex infection in HIV-infected patients with CD4 lymphocyte counts less than or equal to 100/mm³;
- Clarithromycin in the presence of acid suppression is also indicated for the eradication of *H. pylori* resulting in decreased recurrence of duodenal ulcer
- Treatment of odontogenic / dental infections

CLINICAL PHARMACOLOGY

Mechanism of action: Clarithromycin prevents bacteria from growing and interfering with their protein synthesis. Clarithromycin binds to the subunit 50S of the bacteria ribosome and thus inhibits the translation of peptide. Clarithromycin has similar antimicrobial spectrum as erythromycin but is more effective against certain gram-negative bacteria, particularly legionella pneumophila. Besides this bacteriostatic effect, clarithromycin also has bactericidal effect on certain strains such as *Haemophilus influenzae*, *Streptococcus pneumoniae* and *Neisseria gonorrhoeae*.

Pharmacokinetics: Unlike erythromycin, clarithromycin is acid-stable and can therefore be taken orally without being protected from gastric acids. It is readily absorbed, and diffused into most tissues and phagocytes. Due to the high concentration in phagocytes, clarithromycin is actively transported to the site of infection. During active Phagocytosis, large concentrations of clarithromycin are released. The concentration of clarithromycin in the tissues can be over 10 times higher than in plasma. Highest concentrations were found in liver and lung tissue.

Metabolism: Clarithromycin has a fairly rapid first-pass hepatic metabolism. However, 14-hydroxy clarithromycin, clarithromycin's metabolite, is almost twice as active and has a half life of 7 hours. Clarithromycin and its metabolites main routes of elimination are urinary and biliary excretion.

HOW TO USE KLASH FOR BEST RESULTS:

Follow the directions for using this medicine provided by the doctor.

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

TO CLEAR UP YOUR INFECTION COMPLETELY, continue taking this medicine for the full course of treatment even if you feel better in a few days. Do not miss any dose. **IF YOU MISS A DOSE OF THIS MEDICINE,** take it as soon as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

Tablets should be swallowed as a whole and not chewed, broken or crushed.

Dosage: As advised by the doctor. Usually 250-500mg twice or three times daily for 7 to 14 days.

Adverse Drug Reaction: The majority of side effects observed in clinical trials were of a mild and transient nature. Fewer than 3% of adult patients without mycobacterial infections discontinued therapy because of drug-related side-effects. The most common drug-related adverse reactions in adults were nausea, diarrhea, abdominal pain, dyspepsia, headache, taste perversion and vomiting.

CONTRAINDICATIONS: KLASH (Clarithromycin tablet) is contraindicated in patients with a known hypersensitivity to clarithromycin, erythromycin, other macrolide antibacterial agents or to any ingredient in the formulation or component. Clarithromycin is contraindicated as concurrent therapy with astemizole, terfenadin, cisapride, pimozide, ergotamine or dihydroergotamine. There have been post-marketing reports of drug interactions when clarithromycin and/or erythromycin are co-administered with cisapride, astemizole, pimozide, or terfenadine resulting in cardiac arrhythmias (QT prolongation, ventricular tachycardia, ventricular fibrillation, and torsades de pointes) most likely due to inhibition of hepatic metabolism of these drugs by erythromycin and clarithromycin. Fatalities have been reported.

Special Populations

Pregnant Women: The benefits against risk, particularly during the first 3 months of pregnancy should be carefully weighed by a physician; Clarithromycin should not be used in pregnancy except where no alternative therapy is available.

Nursing Women: Clarithromycin is excreted in human milk. Follow precautions

Overdose: If overdose is suspected, contact your doctor or emergency room immediately. Symptoms of overdose may include nausea, vomiting, stomach upset, and diarrhea.

Instructions: Use as prescribed by the doctor. Store below 30°C. Protect from direct sun light, Heat and moisture. Never share your medicines with others, and use this medication only for the indication prescribed.

Pack Size: Klash 250 mg Tab. = 1x10's Blister Pack.

Klash 500 mg Tab. = 1x10's Blister Pack.



Manufactured By:
Aims Pharmaceuticals
Plot # 291, Industrial Triangle, Kahuta Road,
Islamabad-Pakistan