**KLARICID®** (Clarithromycin)  
**125mg/5ml Granules Drops**

**Active ingredients by Formula**

Clarithromycin Granules for Oral Suspension (Granules, Suspension).

**Indications**

Clarithromycin is indicated for the treatment of infections caused by susceptible bacteria and for the treatment of certain infections caused by susceptible fungi.

**Contraindications**

Contraindications include the treatment of infections caused by bacteria or fungi sensitive to clarithromycin, and the treatment of infections caused by bacteria or fungi resistant to clarithromycin.

**Warnings**

A preliminary study of pediatric patients has been reported for the treatment of infections caused by bacteria or fungi resistant to clarithromycin.

**Precautions**

The treatment of infections caused by bacteria or fungi resistant to clarithromycin may require the use of additional agents or the use of alternative treatment regimens.

**Adverse Reactions**

Adverse reactions that may be associated with the treatment of infections caused by bacteria or fungi resistant to clarithromycin are uncommon.

**Dosage and Administration**

Dosage and administration vary depending on the infectious agent and the severity of the condition.

**Laboratory Tests**

The performance of laboratory tests prior to the treatment of infections caused by bacteria or fungi resistant to clarithromycin is recommended.

**Medication History**

The medication history of the patient should be reviewed prior to the treatment of infections caused by bacteria or fungi resistant to clarithromycin.

**Monitoring**

The monitoring of the patient's response to treatment of infections caused by bacteria or fungi resistant to clarithromycin is recommended.

**Drug Interactions**

Drug interactions that may be associated with the treatment of infections caused by bacteria or fungi resistant to clarithromycin are uncommon.

**Dosage Guidelines for Pediatrict Patients Based on Body Weight**

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**Dosing**

The dosing of the medication is based on the patient's weight and the infectious agent.

**Dosage in Children**

Dosage in children varies depending on the infectious agent and the severity of the condition.

**Preparation for Use**

The preparation of the medication for use varies depending on the infectious agent and the severity of the condition.

**Concomitant Administration**

Concomitant administration of the medication and other medications is recommended.

**Drug Interactions**

Drug interactions that may be associated with the treatment of infections caused by bacteria or fungi resistant to clarithromycin are uncommon.

**Contraindications**

Contraindications include the treatment of infections caused by bacteria or fungi resistant to clarithromycin.

**Warnings**

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DRUG INTERACTIONS

Concomitant administration of clarithromycin and other CYP3A4 substrate(s) may result in reduced plasma levels of the CYP3A4 substrate(s). Clarithromycin can alter plasma levels and therapeutic effect of the following drugs:

1. **HMG-CoA reductase inhibitors (statins)**: Lovastatin, simvastatin, atorvastatin, and fluvastatin are CYP3A4 substrates. Co-administration with clarithromycin increases the serum levels of statins, which may increase the risk of myopathy. For patients receiving a dose of simvastatin greater than 40 mg/day or atorvastatin greater than 20 mg/day, the concomitant administration of clarithromycin may increase the risk of myopathy. If a dose oflovastatin or simvastatin greater than 40 mg/day is required, concomitant administration should be avoided. If concomitant administration is necessary, patients should be monitored for signs and symptoms of myopathy. Clarithromycin is contraindicated when co-administered with atorvastatin greater than 20 mg/day and simvastatin greater than 40 mg/day.

2. **HIV protease inhibitors**: Co-administration of protease inhibitors and clarithromycin can result in increased serum levels of clarithromycin andLovastatin. Therefore, concomitant administration is not recommended.

3. **Macrolides**: Clarithromycin should be used with caution when administered concurrently with medications that induce the cytochrome P450 enzyme system, such as rifampicin.

4. **Antidepressants**: Concomitant administration of antidepressants and clarithromycin is not recommended due to the potential for increased risk of serotonin syndrome.

5. **Warfarin**: Clarithromycin can increase the anticoagulant effect of warfarin. INR and prothrombin times should be frequently monitored while patients are receiving clarithromycin and warfarin. Clarithromycin should be used with caution in patients receiving concomitant therapy with warfarin due to the potential for increased bleeding risk.

6. **Oral hypoglycic agents**: Co-administration of clarithromycin and oral hypoglycemic agents can result in significant hypoglycemia. Patients should be monitored for symptoms of hypoglycemia.

7. **Colchicine**: Clarithromycin should not be used concomitantly with colchicine. The concomitant use of these two drugs can result in increased risk of colchicine toxicity.

8. **Fluconazole**: Concomitant administration of fluconazole and clarithromycin can result in increased serum levels of both drugs. Patients should be monitored for signs of toxicity.

9. **Fluvoxamine**: Co-administration of fluvoxamine and clarithromycin can result in increased serum levels of both drugs. Patients should be monitored for signs of toxicity.

10. **Lidocaine**: Concomitant administration of lidocaine and clarithromycin can result in increased serum levels of lidocaine. Patients should be monitored for signs of toxicity.

11. **Methylprednisolone**: Concomitant administration of methylprednisolone and clarithromycin can result in increased serum levels of methylprednisolone. Patients should be monitored for signs of toxicity.

12. **Midazolam**: Clarithromycin can increase the serum levels and effect of midazolam. Patients should be monitored for signs of toxicity.

13. **Ritonavir**: Clarithromycin should not be co-administered with ritonavir due to the potential for increased risk of adverse effects.

14. **Etravirine**: Concomitant administration of etravirine and clarithromycin can result in increased serum levels of both drugs. Patients should be monitored for signs of toxicity.

15. **Colchicine and Ergot alkaloids**: Co-administration of colchicine and ergot alkaloids, such as ergotamine and dihydroergotamine, can result in increased risk of ergot toxicity. Patients should be monitored for signs of toxicity.

16. **Terfenadine and astemizole**: Concomitant administration of terfenadine and astemizole with clarithromycin can result in increased serum levels of both drugs, which can lead to cardiac arrhythmias.

17. **Methotrexate**: Clarithromycin can increase the serum levels and effect of methotrexate. Patients should be monitored for signs of toxicity.

18. **Lithium**: Concomitant administration of lithium and clarithromycin can result in increased serum levels of lithium. Patients should be monitored for signs of toxicity.

19. **Drugs that are inducers of CYP3A (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital, St John’s Wort) may induce the metabolism of clarithromycin and thus decrease the plasma levels of clarithromycin. Patients should be monitored for signs of toxicity.

20. **Drugs that are inhibitors of CYP3A (e.g. ketoconazole, itraconazole) may inhibit the metabolism of clarithromycin and thus increase the plasma levels of clarithromycin. Patients should be monitored for signs of toxicity.

**CONTRAINdications**

- **Methemoglobinemia**: Patients with methemoglobinemia should not receive clarithromycin.
- **Gelatin allergy**: Patients allergic to gelatin should not receive clarithromycin.
- **Hypersensitivity to clarithromycin**: Patients with a history of hypersensitivity to clarithromycin should not receive the drug.
- **Patients with QT interval prolongation**: Patients with a history of QT interval prolongation should not receive clarithromycin.
- **Patients with hepatic impairment**: Patients with severe hepatic impairment should receive clarithromycin with caution.
- **Patients with renal impairment**: Patients with severe renal impairment should receive clarithromycin with caution.

**Precautions**

- **Hypersensitivity reactions**: Patients with a history of hypersensitivity reactions should receive clarithromycin with caution.
- **Hepatitis**: Patients with a history of hepatitis should receive clarithromycin with caution.
- **Renal impairment**: Patients with severe renal impairment should receive clarithromycin with caution.
- **Hepatic impairment**: Patients with severe hepatic impairment should receive clarithromycin with caution.

**ADVERSE REACTIONS**

- **Gastrointestinal**: Nausea, vomiting, diarrhea, abdominal pain, flatulence, constipation, pseudomembranous colitis, and Candida esophagitis have been reported.
- **Respiratory**: Upper respiratory tract infections, sinusitis, pharyngitis, bronchitis, and pneumonia have been reported.
- **Skin and skin appendages**: Rash, urticaria, pruritus, and angioedema have been reported.
- **Miscellaneous**: Headache, dizziness, insomnia, and nightmares have been reported.

**Interactions**

- **Drug-drug interactions**: Concomitant administration of clarithromycin with other drugs may result in altered serum levels and potential adverse effects. Patients should be monitored for signs of toxicity.

**Clinical Pharmacology**

- **Pharmacokinetics**: Clarithromycin is primarily metabolized by CYP3A4 in the liver and excreted in the feces. It has a t1/2 of 70-120 hours.
- **Absorption**: Clarithromycin is well absorbed after oral administration. Absorption is reduced by food and decreases in patients with liver disease.
- **Distribution**: Clarithromycin is widely distributed in body tissues and fluids.
- **Metabolism**: Clarithromycin is metabolized by CYP3A4 in the liver. Metabolites include 14-hydroxy clarithromycin, 15-hydroxy clarithromycin, and 15,16-epoxy clarithromycin.
- **Excretion**: Clarithromycin is excreted in the feces as metabolites and unchanged drug.

**Dosage and Administration**

- **Adults**: The usual adult dose is 500 mg every 12 hours or 250 mg every 8 hours for 10-14 days, depending on the indication.
- **Children**: The recommended dose for children is 25-50 mg/kg/day divided into 2 or 3 doses, depending on the indication.
- **Renal impairment**: Reduced doses are recommended for patients with severe renal impairment.
- **Hepatic impairment**: Reduced doses are recommended for patients with severe hepatic impairment.

**Monitoring**

- **Uveitis**: Patients with a history of uveitis should be monitored for signs of uveitis during treatment with clarithromycin.

**Guidance for Use in Special Populations**

- **Pregnancy**: Clarithromycin is Category B during the first trimester and Category C during the second and third trimesters. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Lactation**: Clarithromycin is excreted in human milk. The potential for adverse effects on the nursing infant justifies discontinuing the drug or the infant.
- **Pediatrics**: Clarithromycin is generally not recommended for infants and children under 12 months of age.

**Overdose**

- **Symptoms**: Nausea, vomiting, diarrhea, abdominal pain, and candidiasis have been reported.
- **Management**: Supportive care should be provided. Gastrointestinal decontamination may be considered.

**Pharmacotherapeutics**

- **Mechanism of Action**: Clarithromycin is a macrolide antibiotic that inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit.
- **Bacterial Susceptibility**: Clarithromycin is active against a wide range of gram-positive and gram-negative bacteria, as well as some fungi and parasites.

**Dosage Forms**

- **Granules for Oral Suspension**: Available in 250 mg and 500 mg strengths.
- **Tablets**: Available in 250 mg and 500 mg strengths.

**Storage**

- **Stability**: Clarithromycin should be stored at room temperature (15-30°C) and protected from light.

**References**


**Additional Resources**

- **Regulatory Information**: FDA drug label for Clarithromycin Granules for Oral Suspension (Pediatric Suspension).
- **Clinical Trials**: ClinicalTrials.gov registration number NCT00123456.
Both clarithromycin and itraconazole are substrates and inhibitors of CYP3A, leading to a bidirectional drug interaction. The dose of clarithromycin should be decreased by 75% using an appropriate clarithromycin formulation. Dose of itraconazole should be decreased by 50%. For patients with creatinine clearance 30 to 60 mL/min (CrCl30–60), the dose of clarithromycin should be decreased by 50%. For patients with creatinine clearance <30 mL/min, the dose of clarithromycin should be decreased by 75%. It is recommended that the dose of itraconazole be decreased by 50%.

Digoxin is thought to be a substrate for the efflux transporter, P-glycoprotein (Pgp). Clarithromycin is known to inhibit the activity of P-glycoprotein. Digoxin concentrations should be carefully monitored while patients are receiving digoxin and clarithromycin simultaneously.

Calcium Channel Blockers

Both clarithromycin and saquinavir are substrates and inhibitors of CYP3A, leading to a bidirectional drug interaction. Saquinavir AUC and Cmax values were approximately 40% higher than those seen with saquinavir alone. Clarithromycin AUC and Cmax are increased by approximately 60% higher than those seen with clarithromycin alone. The drug interaction is reduced when the drug is co-administered intravenously at the same time or at different times.

Colchicine

Colchicine is a substrate for both CYP3A and the efflux transporter, P-glycoprotein (Pgp). Clarithromycin and other CYP3A inhibitors may increase the concentration and duration of action of colchicine, leading to the potential for severe adverse reactions, including pancreatitis, neutropenia, and agranulocytosis. The benefit of the potential increase in colchicine levels must be weighed against the risk of toxicity. A reduction in colchicine dosage may be necessary in the presence of CYP3A inhibitors, such as clarithromycin in the CYP2D6 poor population subset, inhibition of CYP3A results in significantly higher serum concentrations of tolterodine. A reduction in tolterodine dosage may be necessary in the presence of CYP3A inhibitors, such as clarithromycin in the CYP2D6 poor population subset.

Theophylline, carbamazepine

Theophylline is a substrate for CYP1A2 and CYP2C9, and a potent inhibitor of CYP2C9. Clarithromycin is a potent inhibitor of CYP3A. The steady-state concentrations of theophylline were increased by approximately 60% when co-administered with clarithromycin, with a 30% decrease in the clearance of theophylline.

Benzodiazepines

Benzo diazepines which are dependent on CYP3A for their elimination (e.g., midazolam, triazolam, alprazolam) may have increased exposure and a shortened half-life when administered with clarithromycin. Benzodiazepines which are not dependent on CYP3A for their elimination (e.g., diazepam, lorazepam) may have increased exposure when administered with clarithromycin and concentrations should be monitored.

Omeprazole

Clarithromycin (500 mg every 8 hours) was given in combination with omeprazole (40 mg daily) to healthy adult subjects. The steady-state plasma concentrations of omeprazole were increased (Cmax, AUC0-24, and t1/2 increased by 30%, 23%, and 23%, respectively) by the coadministration of clarithromycin. The 24 hour urinary pH (Clarithromycin) was not altered by the coadministration of clarithromycin with omeprazole. The dose of omeprazole should be increased by 150% in the presence of CYP3A inhibitors, such as clarithromycin in the CYP2D6 poor population subset, inhibition of CYP3A results in significantly higher serum concentrations of tolterodine. A reduction in tolterodine dosage may be necessary in the presence of CYP3A inhibitors, such as clarithromycin in the CYP2D6 poor population subset.

Pregnancy and Lactation

There have been post-marketing reports of drug interactions and central nervous system (CNS) effects (e.g., somnolence and agitation) with the use of clarithromycin. There have also been reports of dizziness and vertigo. Clarithromycin should be used with caution in patients receiving treatment with other drugs known to be hepatotoxic.

Hypersensitivity

There have been post-marketing reports of drug interactions and central nervous system (CNS) effects (e.g., somnolence and agitation) with the use of clarithromycin. There have also been reports of dizziness and vertigo. Clarithromycin should be used with caution in patients receiving treatment with other drugs known to be hepatotoxic.

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Clarithromycin has been shown to be active against many of the following respiratory pathogens; in vitro and in clinical studies.

**ADVERSE REACTIONS**

**Microbiologic Properties**

**Pharmacologic Properties**

**Pharmacokinetics**

Clarithromycin is an antibacterial agent by virtue of its high affinity for the 50S ribosomal subunit of susceptible bacteria, resulting in inhibition of peptide bond synthesis and bacterial protein synthesis. The mechanism of action of macrolides is described in more detail in the section Pharmacology and referenced there. The in vitro activity of clarithromycin is bacteriostatic, with the exception of certain strains of Borrelia burgdorferi. The MIC50 and MIC90 for clarithromycin for such strains are 0.125 μg/mL and 0.5 μg/mL, respectively. The minimum inhibitory concentration (MIC) is defined as the lowest concentration that inhibits visible growth of the organism in vitro. MICs should be determined using a standardized laboratory procedure. For the in vitro testing of antimicrobial activity, standardized procedures utilizing Mueller-Hinton broth, agar, or gel dilution methods should be used.

**Pharmacology**

Clarithromycin is a macrolide antibiotic that inhibits bacterial protein synthesis. It is a broad-spectrum antibiotic that is effective against a wide range of infections caused by susceptible bacteria. Clarithromycin is a member of the 14-membered macrolide class of antibiotics and is structurally similar to erythromycin.

**Clinical Use**

Clarithromycin is effective against a wide range of infections caused by susceptible bacteria. It is commonly used to treat infections caused by aerobic and anaerobic Gram-positive and Gram-negative bacteria, as well as some mycobacteria and spirochetes. Clarithromycin is also effective against certain fungi and viruses.

**Pharmacokinetics**

Clarithromycin is rapidly absorbed after oral administration and has a half-life of approximately 2 hours. It is extensively metabolized in the liver and excreted in the urine. The major metabolite is 14-deoxy-14-ethyl clarithromycin. The metabolism of clarithromycin is unaffected by the CYP3A4 isoenzyme, and the drug is not a substrate for the P-glycoprotein transporter. Clarithromycin is primarily excreted in the urine, with less than 10% excreted in the feces. Clarithromycin is considered to be highly protein bound, with a binding capacity of greater than 95%.

**Preclinical Study**

Clarithromycin was studied in preclinical models, including toxicity studies in animals and in vitro studies. It was found to be safe and effective in these studies, and the results supported its use in clinical trials.

**Clinical Studies**

Clarithromycin has been extensively studied in clinical trials, and it has been shown to be effective in the treatment of a wide range of bacterial infections. The drug is generally well tolerated, with the most common side effects being gastrointestinal in nature. Clarithromycin is available in several formulations, including oral suspension, granules for oral suspension, and injection. It is typically administered by mouth, but it can also be administered intravenously in hospital settings.

**Warnings and Precautions**

Clarithromycin is generally well tolerated, but it can cause certain side effects. These include gastrointestinal symptoms such as nausea, vomiting, and diarrhea. Other potential side effects include rash, headache, and fever. Clostridium difficile infection, a rare but serious complication, has been reported with the use of clarithromycin and other macrolide antibiotics. It is important to monitor patients for these potential side effects and to discontinue the drug if necessary.

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