clarithromycin (klä-rith-roe-my-sin)
Biaxin, Biaxin XL

**Classification**
Therapeutic: agents for atypical mycobacterium, anti-infectives, antiulcer agents
Pharmacologic: macrolides

**Pregnancy Category C.**

**Indications**

**Action**
Inhibits protein synthesis at the level of the 50S bacterial ribosome.

**Therapeutic Effects:**
Bacteriostatic action.

**Spectrum:**
Active against these gram-positive aerobic bacteria: Staphylococcus aureus, Staphylococcus pneumoniae, S. pyogenes (group A strep). Active against these gram-negative aerobic bacteria: Haemophilus influenzae, Moraxella catarrhalis. Also active against: Mycoplasma, Legionella, H. pylori, H. avium.

**Pharmacokinetics**
Absorption: Rapidly absorbed (50%) after oral administration.

Distribution:
Widely distributed; tissue levels may exceed those in serum.

Protein Binding: 65–70%.

Metabolism and Excretion:
10–15% converted by the liver to 14-hydroxyclarithromycin, which has anti-infective activity; 20–30% excreted unchanged in urine. Metabolized by and also inhibits the CYP3A enzyme system.

Half-life:
Dose-dependent and prolonged with renal dysfunction 250-mg dose — 3–4 hr; 500-mg dose — 5–7 hr.

**TIME/ACTION PROFILE (serum levels)**

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO</td>
<td>unknown</td>
<td>2 hr</td>
<td>12 hr</td>
</tr>
<tr>
<td>PO-XL</td>
<td>unknown</td>
<td>4 hr</td>
<td>24 hr</td>
</tr>
</tbody>
</table>

**Contraindications/Precautions**
Contraindicated in: Hypersensitivity to clarithromycin, erythromycin, or other macrolide anti-infectives; History of cholestatic jaundice or hepatic dysfunction with clarithromycin; Concurrent use of pimozide, ergotamine, dihydroergotamine, levamezalam, sumatriptan, quinidine, procainamide, dofetilide, amiodarone, or sotalol; Concurrent use of colchicine in patients with hepatic or renal impairment; QT interval prolongation, hypokalemia, hypomagnesemia, or bradycardia; CMB should use during pregnancy unless no alternatives are available. 

**Use Cautiously in:** Severe liver or renal impairment (dose adjustment required if CCr < 30 mL/min); Myasthenia gravis; May have risk of QT interval prolongation.

**Adverse Reactions/Side Effects**

**CNS:**
Headache.

**CV:**
TORSADES DE POINTES, QT interval prolongation.

**Derm:**
Stevens-Johnson syndrome, pruritus, rash.

**GI:**
Hepatotoxicity, pseudomembranous colitis, abdominal pain/discomfort, abnormal taste, diarrhea, dyspepsia, nausea.

**Interactions**

**Drug-Drug:**
Clarithromycin is an inhibitor of the CYP3A enzyme system. Concurrent use with other agents metabolized by this system can cause levels and risk of toxicity. May prolong the QT interval and risk of arrhythmias with pimozide; concurrent use contraindicated. May increase levels of ergotamine and dihydroergotamine and risk for acute ergot toxicity; concurrent use contraindicated. Quinidine, procainamide, dofetilide, sotalol, and amiodarone may prolong the QT interval; concurrent use should be avoided. May increase levels of carbamazepine, cyclosporine, felodipine, omeprazole, tacrolimus, digoxin, theophylline, and midazolam. May increase levels and effects of omeprazole. May increase levels of lovastatin and simvastatin; concurrent use contraindicated. May increase levels and risk of toxicity from carbamazepine, some benzodiazepines (midazolam, triazolam, alprazolam), cyclosporine, disopyramide, quinidine, and colchicine in patients with CCr < 30 mL/min. May increase levels and risk of toxicity from digoxin.

**Monitoring:**
Levels of clarithromycin in chronic users of CMB should be monitored. Initial levels indicate most frequent side effects.
2

From atorvastatin and pravastatin, use lowest dose of these agents, do not exceed atorvastatin dose of 20 mg/day or pravastatin dose of 40 mg/day. May \( q \) or \( p \) effects of zidovudine. Blood levels are \( q \) by delavirdine and fluconazole. Blood levels may \( q \) by rifampin, rifabutin, efavirenz, and nevirapine. Concurrent use with atazanavir levels and risk of toxicity from colchicine; \( q \) or \( p \) effects of sildenafil, tadalafil, and vardenafil; concurrent use not recommended. May \( q \) levels of tolterodine. Concurrent use with clarithromycin and atazanavir levels; \( q \) clarithromycin dose by 50%. Concurrent use with clarithromycin and itraconazole levels. Concurrent use with saquinavir may \( q \) clarithromycin and saquinavir levels. Concurrent use with clarithromycin and atazanavir levels; \( q \) clarithromycin dose by 50%. Concurrent use with clarithromycin and itraconazole levels. Concurrent use with saquinavir may \( q \) clarithromycin and saquinavir levels.

Route/Dosage

PO (Adults): Pharyngitis/tonsillitis—250 mg \( q \) 12 hr for 10 days; Acute maxillary sinusitis—500 mg \( q \) 12 hr for 14 days or 1000 mg once daily for 14 days as XL tablets; Acute exacerbation of chronic bronchitis—250–500 mg \( q \) 12 hr for 7–14 days or 1000 mg once daily for 7 days as XL tablets; Community-acquired pneumonitis—250 mg \( q \) 12 hr for 7–14 days or 1000 mg once daily for 7 days as XL tablets; Acute streptococcal pharyngitis/tonsillitis—250 mg \( q \) 12 hr for 7–14 days; \( H. \) pylori—500 mg \( q \) 2–3 times daily with a proton pump inhibitor (lansoprazole or omeprazole) or ranitidine with or without amoxicillin for 10–14 days; Endocarditis prophylaxis—500 mg 1 hr before procedure; MAC prophylaxis/treatment—500 mg \( q \) 2 times daily, for active infection another antimycobacterial is required.

PO (Children): Most infections—15 mg/kg/day divided \( q \) 12 hr for 7–14 days (up to 500 mg/dose for MAC).

Renal Impairment

PO (Adults): CCr <30 mL/min—250 mg \( q \) 1–2 times daily, a 500 mg initial dose may be used.

PO (Children): CCr <30 mL/min—decrease dose by 50% or double dosing interval.

NURSING IMPLICATIONS

Assessment

- Assess patient for infection (vital signs, appearance of wound, sputum, urine, and stool; WBC) at beginning of and during therapy.
- Obtain specimens for culture and sensitivity before initiating therapy. First dose may be given before receiving results.
- Monitor bowel function. Diarrhea, abdominal cramping, fever, and bloody stools should be reported to health care professional promptly as a sign of pseudomembranous colitis. May begin up to several weeks following cessation of therapy.
- Assess patient for skin rash frequently during therapy. Discontinue clarithromycin at first sign of rash, may be life-threatening. Stevens-Johnson syndrome may develop. Treat symptomatically; may recur once treatment is stopped.
- Ulcers: Assess patient for epigastric or abdominal pain and frank or occult blood in the stool, vomiting, or gastric aspirate.
- Lab Test Considerations: May rarely cause \( q \) serum AST, ALT, total bilirubin, and alkaline phosphatase concentrations.
- May occasionally cause \( p \) BUN.

Potential Nursing Diagnoses

- Risk for infection (Indications) (Side Effects)
- Noncompliance (Patient/Family Teaching)

Implementation

- PO: Administer around the clock, without regard to meals, may be administered with milk. Final dose but does not decrease the extent of absorption.
- Administer XL tablets with food or milk; do not crush, break or chew.
- Shake suspension well before administration. Store suspension at room temperature; do not refrigerate.
- Do not administer within 4 hr of zidovudine.

Patient/Family Teaching

- Instruct patient to take medication around the clock and to finish the drug completely as directed, even if feeling better. Take missed doses as soon as possible, unless almost time for next dose. Do not double doses. Advise patient that sharing of this medication may be dangerous.

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CONTINUED
clarithromycin

● Advise patient to report signs of superinfection (black, furry overgrowth on the tongue; vaginal itching or discharge; loose or foul-smelling stools).
● Instruct patient to notify health care professional if rash, or fever and diarrhea develop, especially if stool contains blood, pus, or mucus. Advise patient not to treat diarrhea without consulting health care professional.
● Caution patients taking indinavir that clarithromycin and indinavir must be taken at least 4 hr apart.
● Advise patient to notify health care professional immediately if pregnancy is planned or suspected or if breast feeding.
● Instruct the patient to notify health care professional if symptoms do not improve within a few days.

Evaluation/Desired Outcomes
● Resolution of the signs and symptoms of infection. Length of time for complete resolution depends on the organism and site of infection.
● Treatment of ulcers.
● Endocarditis prophylaxis.

Why was this drug prescribed for your patient?