

LOUD

Tablets/Dry Suspension

گولیاں/ڈرائی سسپنشن
لاؤڈ

DESCRIPTION:

Clarithromycin is a semi-synthetic macrolide antibiotic. Chemically, it is 6-O-methylerythromycin.

QUALITATIVE & QUANTITATIVE COMPOSITION:

LOUD 250mg Tablet

Each film coated tablet contains:
Clarithromycin USP.....250mg
(Product Specs.: USP)

LOUD 500mg Tablet

Each film coated tablet contains:
Clarithromycin USP.....500mg
(Product Specs.: USP)

LOUD 125mg/5mL Dry Suspension

Each 5mL of reconstituted suspension contains:
Clarithromycin enteric coated taste masked granules eq. to Clarithromycin.....125mg
(Product Specs.: USP)

LOUD 250mg/5mL Dry Suspension

Each 5mL of reconstituted suspension contains:
Clarithromycin enteric coated taste masked granules eq. to Clarithromycin.....250mg
(Product Specs.: USP)

CLINICAL PHARMACOLOGY:

Mode of Action:

Clarithromycin prevents bacteria from growing, by interfering with their protein synthesis. Clarithromycin binds to the subunit 50S of the bacterial ribosome, and thus inhibits the translocation of peptides, resulting in inhibition of protein synthesis.

Microbiology:

Clarithromycin has been shown to be active against the following microorganisms.
Aerobic gram-positive microorganisms:
Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes.

Aerobic gram-negative microorganisms:

Haemophilus influenzae, Haemophilus parainfluenzae, Moraxella catarrhalis.

Mycobacteria:

Mycobacterium avium complex (MAC) (consisting of: Mycobacterium avium: Mycobacterium intracellulare).

Helicobacter:

Helicobacter pylori.

Other microorganisms:

Mycoplasma pneumoniae, Chlamydia pneumoniae.

Pharmacokinetics:

Clarithromycin is rapidly absorbed by the gastrointestinal tract following oral administration and under goes first pass metabolism. The extent of bioavailability is relatively unaffected by the presence of food. The bioavailability of the suspension is identical to or slightly higher than the bioavailability of the tablets. The drug and its principal metabolites are widely distributed and tissue concentrations exceed those in serum, in part because of intracellular uptake. Clarithromycin is extensively metabolized in liver and excreted in feces via bile. Substantial amounts are excreted in urine, at steady state about 20% and 30% respectively of a 250mg or 500mg dose is excreted in this way as unchanged drug. 14-Hydroxyclarithromycin as well as other metabolite is also excreted in the urine accounting for 10 to 15% of the dose. The terminal half-life of clarithromycin is reportedly about 3 to 4 hours in patients receiving 250mg doses twice daily and about 5 to 7 hours in those receiving 500mg twice daily.

Special Population:

Renal insufficiency:

The half-life is prolonged in renal impairment. Use with caution with renal impairment patients.

INDICATIONS:

LOUD (Clarithromycin) is indicated for treatment of following infections: -

- Lower respiratory tract infections (e.g., bronchitis, pneumonia)

- Upper respiratory tract infections (e.g., pharyngitis, sinusitis, tonsillitis)

- Acute otitis media in children

- Skin and soft tissue infections (e.g., folliculitis, cellulitis, erysipelas, impetigo, abscesses)

- Disseminated or localized mycobacterial infections due to MAC

- To eradicate Helicobacter pylori in treatment regimens for peptic ulcer disease

- To prevent disseminated Mycobacterium avium complex (MAC) disease in patients with advanced HIV infection

DOSEAGE AND ADMINISTRATION:

Adults:

The usual recommended dosage of LOUD (Clarithromycin) is 250mg tablet twice daily. In more severe infections the dosage can be increased to 500mg twice daily. The usual duration of therapy is 7 to 14 days.

LOUD (Clarithromycin) suspension may be used as an alternative dosage form for those adults that prefer a liquid medicine.

ADULT DOSSAGE GUIDELINES		
INFECTION	DOSSAGE (q12hr)	NORMAL DURATION (DAYS)
PHARYNGITIS/TONSILLITIS DUE TO:		
S. pyogenes	250mg	10
ACUTE MAXILLARY SINUSITIS DUE TO:		
H. influenzae	500mg	14
M. catarrhalis	500mg	14
S. pneumoniae	500mg	14
ACUTE EXACERBATION OF CHRONIC BRONCHITIS DUE TO:		
H. influenzae	500mg	7 to 14
H. parainfluenzae	500mg	7
M. catarrhalis	250mg	7 to 14
S. pneumoniae	250mg	7 to 14
COMMUNITY ACQUIRED PNEUMONIA DUE TO:		
H. influenzae	250mg	7
S. pneumoniae	250mg	7 to 14
C. pneumoniae	250mg	7 to 14
M. pneumoniae	250mg	7 to 14
UNCOMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS DUE TO:		
S. aureus	250mg	7 to 14
S. pyogenes	250mg	7 to 14
PEPTIC ULCER DUE TO:		
Helicobacter Pylori	LOUD 500mg b.i.d. with another antibacterial and either a proton pump inhibitor or a histamine H2-receptor antagonist	7 to 14
FOR THE PROPHYLAXIS AND TREATMENT OF DISSEMINATED MYCOBACTERIAL INFECTIONS DUE TO:		
Mycobacterium Avium Complex	LOUD 500mg b.i.d. + with other anti mycobacterial drugs with activity against MAC	

Children:

The usual recommended dosage of LOUD (Clarithromycin) is 7.5mg/kg twice daily up to a maximum of 500mg twice daily. The usual duration of treatment is for 5 to 10 days depending on the pathogen involved and severity of the condition.

PEDIATRIC DOSAGE GUIDELINES (BASED ON BODY WEIGHT)			
Weight in kg	Dosage in mg	Dosage in mL 125mg/5mL	Dosage in mL 250mg/5mL
8 - 11	62.5mg b.i.d.	2.5mL (1/2 tsp b.i.d.)	1.25mL b.i.d. (1/4 tsp b.i.d.)
12 - 19	125mg b.i.d.	5 mL (1 tsp b.i.d.)	2.5mL b.i.d. (1/2 tsp b.i.d.)
20 - 29	187.5mg b.i.d.	7.5mL (1.5 tsp b.i.d.)	3.75mL b.i.d. (3/4 tsp b.i.d.)
30 - 40	250mg b.i.d.	10mL (2 tsp b.i.d.)	5mL b.i.d. (1 tsp b.i.d.)
*Children <8kg should be based on a per kg basis (approx. 7.5mg/kg b.i.d.)			

Hepatic and renal impairment: Clarithromycin may be administered without dosage adjustment in the presence of hepatic impairment if there is normal renal function. At creatinine clearance < 30mL/min, the dosage should be halved to 250mg daily or in the most severe infections to 250mg twice daily for adults and 7.5mg/kg once a day for children. The duration of treatment should not exceed 14 days in these patients.

Directions for Preparation of Dry Suspension:

- Fill previously boiled and cooled water up to the mark on the bottle and shake gently

- Do not refrigerate the reconstituted suspension

- The reconstituted suspension can be used for up to 14 days, when store at room temperature

CONTRAINDICATIONS:

- Clarithromycin is contraindicated in patients with a known hypersensitivity to Clarithromycin, erythromycin or any of the macrolide antibiotics

- Concomitant administration with cisapride, pimozide, astemizole, terfenadine, and ergotamine or dihydroergotamine

PRECAUTION:

- Pseudomembranous colitis has been reported with macrolides. Therefore, it is important to consider its diagnosis in patients who develop severe diarrhea during or after therapy with Clarithromycin

Pregnancy:

Clarithromycin should not be used during pregnancy unless there is a clinical necessity.

Nursing Mothers:

Clarithromycin and its active metabolite are excreted in breast milk. Therefore, diarrhea and fungus infection could occur in the breast-fed infant, so that nursing might have to be discontinued. The benefit of treatment of the mother should be weighed against the potential risk for the infant.

DRUG INTERACTIONS:

The metabolism of other drugs by the hepatic cytochrome P450 3A (CYP3A) isozyme system may be inhibited by concomitant administration with clarithromycin and may be associated with elevations in serum levels of drug classes known or suspected to be metabolized by the same CYP450 and CYP3A isozyme

- Elevated digoxin serum concentrations have been reported in patients receiving clarithromycin and digoxin concomitantly. Monitoring of serum digoxin levels should be considered

- Torsades de pointes may be reported with concurrent use of clarithromycin and quinidine or disopyramide. Serum levels of these medications should be monitored

- Simultaneous oral administration of clarithromycin tablets and zidovudine to HIV-infected adult patients may result in decreased steady-state zidovudine concentrations

ADVERSE REACTIONS:

The following side effects were reported with the use of Clarithromycin:
Common: Oral monilia, headache, nausea, diarrhea, vomiting, abdominal pain, dyspepsia, stomatitis, glossitis, reversible tooth and tongue discoloration, and taste perversion.

Uncommon: Decreased leucocyte levels, allergic reactions, hepatitis and cholestasis with or without jaundice.

OVERDOSAGE:

Over dosage of clarithromycin can cause gastrointestinal symptoms such as abdominal pain, vomiting, nausea, and diarrhea. Adverse reactions accompanying overdosage should be treated by the prompt elimination of unabsorbed drug and supportive measures.

As with other macrolides, clarithromycin serum concentrations are not expected to be appreciably affected by hemodialysis or peritoneal dialysis.

INSTRUCTIONS:

- Store below 30°C

- Protect from light & moisture

- Keep out of reach of children

To be sold on prescription of a registered medical practitioner only.

HOW SUPPLIED:

LOUD (Clarithromycin) 250mg Tablets are available in pack of 10's.

LOUD (Clarithromycin) 500mg Tablets are available in pack of 10's.

LOUD (Clarithromycin) 125mg/5mL Dry Suspension is available in pack of 30mL PET bottle.

LOUD (Clarithromycin) 250mg/5mL Dry Suspension is available in pack of 60mL PET bottle.

LOUD (Clarithromycin) 250mg/5mL Dry Suspension is available in pack of 60mL PET bottle.

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایت : دوا کو ۳ گھنٹے کی وقفے پر لیتے ہیں کہ درجہ حرارت پر رکھیں۔

روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

**SIGMA
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