Dar Al Dawa

Claridar® Dar Al Dawa clarithromycin

DESCRIPTION: Claridar® (Clarithromycin) is a semi-synthetic macrolide antibiotic, which is active against a variety of aerobic and anaerobic gram-positive and gram-negative microorganisms.

Pharmacology: Clarithromycin is rapidly absorbed from the gastrointestinal tract after an oral administration. Food slightly delays both the onset of clarithromycin absorption and the formation of the antimicrobially active metabolite, 14-OH clarithromycin, but does not affect its bioavailability. In fasting healthy human subjects, peak serum concentrations were attained within 2 hours after oral dosing. Steady-state peak serum clarithromycin concentrations were attained in 2-3 days and were approximately 1µg/ml with a 250mg dose administered every 12 hours, 2 to 3 µg/ml with a 500 mg dose administered every 12 hours and 3 to 4 µg/ml with 500 mg dose administered every 8 hours.

The elimination half-life of clarithromycin was about 3 to 4 hours with 250 mg administered every 12 hours but increased 5 to 7 hours with 500mg administered every 8 - 12 hours. After a 250mg-tablet every 12 hours, approximately 20% of the dose is excreted in the urine as clarithromycin, while after a 500mg tablet every 12 hours urinary excretion is approximately 30%. After an oral dose of 250mg (125mg/5ml) suspension every12 hours, approximately 40% is excreted in urine as clarithromycin. The renal clearance of clarithromycin is, however, relatively independent of the dose size and approximates the normal glomerular filtration rate. Half-life is prolonged in renal failure.

INDICATIONS: For the treatment of mild to moderate infections caused by susceptible strains of designated microorganisms in the following conditions:

Adults and children:

- Pharyngitis/ Tonsillitis caused by *S. pyogenes*.
- Acute bacterial exacerbation of chronic bronchitis, caused by *H. influenzae*, *M. catarrhalis*, or *S. pneumoniae*.
- Acute maxillary sinusitis caused by *H. influenzae*, *M. catarrhalis* or *S. pneumoniae*.
- Pneumoniae caused by *Mycoplasma pneumoniae*, *S. pneumoniae*, or *Chlamydia pneumoniae*.
- Uncomplicated skin and skin structure infections caused by *S. aureus*, *S. pyogenes*. Abscesses usually require surgical drainage.
- Disseminated mycobacterial infections caused by *bacterium avium* or *Mycobacterium intracellulare*.
- Prevention of disseminated *Mycobacterium avium* complex disease in patients with advanced HIV infection (see dosage for children).
- *H. pylori* double therapy: clarithromycin in combination with omeprazole is indicated for the treatment of patients with an active duodenal ulcer associated with *H. pylori* infection.
- *H. pylori* triple therapy: clarithromycin, omeprazole and Amoxicillin as combination triple therapy for the treatment of *H. pylori* infection and duodenal ulcer disease (active or 1 year history of duodenal ulcer) to eradicate *H. pylori*.

CONTRAINDICATIONS: Clarithromycin is contraindicated in patients with a known hypersensitivity to clarithromycin or any of the macrolide antibiotics. Clarithromycin is also contraindicated when administered concomitantly with: cisapride, pimozide or terfenadine. Clarithromycin is also contraindicated in pregnant women.

SIDE EFFECTS: The majority of side effects observed in clinical trials were of a mild and transient nature. The most frequently reported side effects in adults were diarrhea, nausea, abnormal taste, dyspepsia, abdominal pain or discomfort and headache; their frequency ranged between 2 and 3 percent. In pediatric patients the most frequently reported events were diarrhea, vomiting, abdominal pain, rash and headache. Other reactions have been reported such as allergic reactions ranging from urticaria and skin eruption to rare cases of anaphylaxis and Steven-Johnson syndrome. Transient CNS events including anxiety, confusional states, disorientation and insomnia, were also reported.

PRECAUTIONS:

- Pseudomembranous Colitis: has been associated with all antibacterial agents including clarithromycin and may range in severity from mild to severe.
  Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.
- Clarithromcyin is principally excreted via the liver and kidney. Clarithromycin may be administered without dosage adjustment to patients with hepatic impairment and normal renal function.
- Clarithromycin in combination with ranitidine bismuth citrate therapy* is not recommended in patients with creatinine clearance less than 25ml/min, or in patients with history of acute porphyria.
- Pregnancy: there are no adequate and well controlled studies in pregnant women. Clarithromycin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing mother: It is not known whether clarithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when clarithromycin is administered to nursing women.
- Pediatric use: safety and effectiveness of clarithromycin in children under 6 months of age have not been established.

DRUG INTERACTIONS:

- Theophylline: clarithromycin use in patients who are receiving theophylline may be associated with an increase serum theophylline concentrations.
- Carbamazepine: Concomitant administration of single doses of clarithromycin and carbamazepine has been shown to result in increase plasma concentration of carbamazepine.
  Blood level monitoring of carbamazepine may be considered.
- Terfenadine: when clarithromycin and terfenadine were co-administered, plasma concentrations of the active acid metabolite of terfenadine were three fold higher, on average, than the values observed when terfenadine was administered alone.
- Zidovudine: concomitant administration of clarithromycin and zidovudine to HIV infected adult patients resulted in decreased steady-state zidovudine concentrations. When clarithromycin tablets were administered two to four hours prior to oral zidovudine, the steady-state zidovudine Cmax was increased by 2-folds whereas the AUC was unaffected.
- Fluconazole: concomitant administration of fluconazole 200mg daily and clarithromycin 500 mg twice daily to 21 healthy volunteers, led to increases in the mean steady-state clarithromycin (C max and AUC of 33% and 18% respectively). Steady-state concentrations of 14-OH clarithromycin were not significantly affected by concomitent administration of fluconazole.
- Digoxin: Elevated digoxin serum concentrations in patients receiving clarithromycin and digoxin concomitantly have been reported. Some patients have shown clinical signs consistent with digoxin toxicity including arrhythmias. Serum digoxin levels should be carefully monitored while patients are receiving digoxin and clarithromycin simultaneously.
- Ergotamine: concurrent use of erythromycin or clarithromycin and ergotamine or dihydroergotamine has been associated in some patients with acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia.
- Other drugs: the use of erythromycin or clarithromycin in patients concurrently taking drugs metabolized by cytochrome P450 system may be associated with elevations in serum levels, these drugs: cyclosporine, tacrolimus, hexobarbital, phenytoin, alfentanil, disopyramide, lovastatin, bromocriptine, valproate, terfenadine, cisapride, pimozide, and astemizole. Serum concentrations of these drugs should be monitored closely in patients concurrently receiving these drugs.

DOSAGE:

Claridar® film-coated tablets and powder for oral suspension may be given with or without food. The usual dose is 250mg twice daily, increased to 500mg twice daily if necessary in severe infections. A course is usually for 7 to 14 days. Patients with renal impairment dosage may need to be halved to 250 mg twice daily in severe infection.

Adult dosage guidelines

Infection	Dosage (12 hours)	Normal duration (days)
Pharyngitis/Tonsillitis	250 mg	10 days
Acute maxillary sinusitis	500 mg	14 days
Acute exacerbation of chronic bronchitis due to: S. pneumonia , M. catarrhalis, H. influanzae	 250 mg 500 mg	 7-14 days 7-14 days
Pneumoniae due to: S. pneumoniae ,M. pneumoniae	 250 mg	 7-14 days
Uncomplicated skin and skin structure	250 mg	7-14 days

Children: The usual recommended daily Dosage is 15-mg/kg/day divided q 12h. for 10 days.

Based on body weight		
Weight (kg)	**Dosage (q 12h)**	**125mg / 5ml**
5-10	62.5 mg	2.5 ml/q 12h
11-20	125 mg	5 ml/q 12h
21-30	187.5 mg	7.5 ml/q 12h

Active duodenal ulcer associated with H. Pylori infections

DUAL THERAPY	DURATION	TRIPLE THERAPY	DURATION
Clarithromycin 500 mg tablet b.i.d. Plus Omeprazole 40mg tablet every morning. Omeprazole 40mg every morning.	Days 1-14 Days 15-28	Clarithromycin 500 mg tablet b.i.d. Plus. Amoxycillin 1000 mg b.i.d. Plus Omeprazole 20 mg every morning.	10 Days

OVERDOSAGE:

In case of overdosage, clarithromycin should be discontinued. Overdosage should be handled with prompt elimination of unabsorbed drug and all other appropriate measures should be instituted. Clarithromycin is not removed by peritoneal dialysis or hemodialysis.

PRESENTATIONS:

Claridar® 250: Film Coated Tablets. Packs of 14 tablets. Each tablet contains 250 mg Clarithromycin.
Claridar® 500: Film Coated Tablets. Packs of 14 and 20 Tablets. Each tablet contains 500 mg Clarithromycin.
Claridar® 125: Powder for Oral Suspension of 60 ml. Each 5 ml (teaspoonful) contains 125 mg Clarithromycin.

STORAGE CONDITIONS :

Tablets and suspension: Store up to 30°C.
The reconstituted suspension can be stored at room temperature (15-30 C°) for 14 days.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, it's benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you .
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

10/02

Manufactured by Dar Al Dawa , Na'ur - Jordan