Dar Al Dawa

DAROXIME®

(Cefuroxime Axetil)

DESCRIPTION :

Daroxime® (Cefuroxime Axetil) is an orally administered antibiotic. It contains cefuroxime axetil as a prodrug for the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative bacteria.

PHARMACOLOGY :

Cefuroxime axetil is absorbed from the GIT and rapidly hydrolyzed by nonspecific esterases in the intestinal mucosa and blood to cefuroxime. Cefuroxime is subsequently distributed throughout the extracellular fluids. Approximately 50% of serum cefuroxime is bound to plasma protein. Absorption of cefuroxime axetil is enhanced when taken with food, nevertheless, the clinical and bacteriological responses of patients were independent of food intake. Peak serum cefuroxime levels occured two to three hours after oral dosing. The serum half-life in plasma is about 1.2 hours.

Cefuroxime is excreted unchanged in the urine, approximately 50 % of the administered doses is recovered in the urine within 12 hours.

INDICATIONS :

Daroxime® is indicated in the following infections:

- Pharyngitis and tonsillitis caused by *S.pyogenes.*
- Otitis media (acute bacterial infection) caused by *S. pneumoniae, H. influenzae* (including ß lactamase producing strains), *M.catarrhalis* and *S. pyogenes.*
- Maxillary Sinusitis (acute) caused by *S.pneumoniae* or *H .influenzae* (effectiveness still not evaluated).
- Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis caused by *S.pneumoniae, H.influenzae* or *H. parainfluenzae.*
- Urinary tract infections (uncomplicated) caused by *E. coli* or *K. pneumoniae.*
- Skin and skin structure infections (uncomplicated) caused by *S. aureus* (including ß lactamase producing strains) and *S.pyogenes.*
- Uncomplicated gonorrhea (urethral and endocervical) caused by penicillinase producing and non-pencillinase producing strains of *N. gonorrhea.*
- Impetigo in children caused by *S.aureus or S. pyogenes.*

CONTRAINDICATIONS :

Daroxime® is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

SIDE EFFECTS :

The following adverse reactions may occasionally accompany cefuroxime axetil administration, but they are generally mild and transient: Hypersensitivity reactions including rash, urticaria, pruritus and anaphylaxis. Gastrointestinal disturbances such as nausea, vomiting and diarrhea.

PRECAUTIONS:

- Cross-hypersensitivity among ß-lactam antibiotics has been clearly documented, so careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to similar products or not. If a clinically significant allergy reaction to cefuroxime axetil occurs, discontinue the drug and appropriate therapy should be instituted.
- As with other broad-spectrum antibiotics, prolonged administration of cefuroxime axetil may result in superinfection during therapy, if encountered, appropriate measures should be taken.
- Cephalosporins, including cefuroxime axetil should be given with caution to patients receiving concurrent treatment with potent diuretics, because these diuretics are suspected of adversely affecting renal function.
- Cefuroxime axetil tablets should be swallowed as a whole, not crushed, since the crushed tablet has a strong, persistent bitter taste. Children who cannot swallow the tablet whole should receive the oral suspension.
- Cefuroxime may cause a false-positive reaction for urine glucose but not with enzyme-based tests. Also it may cause a false-negative reaction in the ferricyanide test for blood glucose.
- A false positive direct Coombs' test has occurred in some patients receiving cephalosporins. This reaction is non-immunological.

Pregnancy:

There are no adequate and well controlled studies about usage of cefuroxime axetil in pregnant women. Cefuroxime axetil should be used during pregnancy only if clearly needed.

Nursing mothers:

Because cefuroxime is excreted in human milk, consideration should be given to discontinue nursing temporarily during treatment with **Daroxime®**.

DRUG INTERACTIONS:

Probenecid may increase and prolong cefuroxime plasma levels by competitively inhibiting renal tubular secretion.

DOSAGE & ADMINISTRATION:

Daroxime® tablets and suspension are not bioequivalent and are not substitutable on a mg/mg basis.

Dosage for Daroxime Tablets

Population/Infection Adult (>13 years)	Dosage	Duration(days)
Pharyngitis/tonsillitis	250 mg bid	10
Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis.	250 or 500 mg bid	10
Uncomplicated skin and skin structure infections.	250 or 500 mg bid	10
Uncomplicated urinary tract infectins.	125 or 250 mg bid	7 to 10
Uncomplicated gonorrhea.	1000 mg (once)	single dose
Children who can swallow tablets whole:		
Pharyngitis/ tonsillitis	125 mg bid	10
Acute otitis media.	250 mg bid	10

Dosage for Daroxime Suspension

Population / infection (infants and children, 3 months to 12 years)	Dosage	maximum Daily dose	Duration (days)
Pharyngitis/tonsillitis	20 mg/kg/day divided (bid)	500 mg	10
Acute otitis media	30 mg/kg/day divided (bid)	1000 mg	10
Impetigo	30 mg/kg/day divided (bid)	1000 mg	10

OVERDOSAGE:

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

PRESENTATIONS:

Daroxime® Film-Coated Tablets 125 mg, pack of 10 tablets: Each tablet contains 125 mg Cefuroxime (as cefuroxime axetil).
Daroxime® Film-Coated Tablets 250 mg, pack of 10 tablets: Each tablet contains 250 mg Cefuroxime (as cefuroxime axetil).
Daroxime® Film-Coated Tablets 500 mg, pack of 10 tablets: Each tablet contains 500 mg Cefuroxime (as cefuroxime axetil).
Daroxime® Suspension 125 mg, Bottle of 50 ml : Each 5 ml contains 125 mg Cefuroxime (as cefuroxime axetil).

STORAGE CONDITIONS :

For tablets: Store in a dry place between 15-30˚C.
For suspension : Store below 30˚C . After reconstitution, Store in a refrigerator (2-8˚C) and discard unused portion after 10 days.
Shake well before use.

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

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Manufactured by Dar Al Dawa , Na'ur - Jordan