

CEFGARD

(Cefaclor) USP

CAPSULES

SUSPENSION

DROPS

CEFGARD is a broad spectrum cephalosporin antibiotic, containing (Cefaclor) USP. Available in following presentations.

CEFGARD 250mg Capsules

Each capsule contains (Cefaclor) USP.....250mg

CEFGARD 500mg Capsules

Each capsule contains (Cefaclor) USP.....500mg

CEFGARD 125mg Suspension

Each 5ml reconstituted suspension contains (Cefaclor) USP.....125mg

CEFGARD FORTE 250mg Suspension

Each 5ml of reconstituted suspension contains (Cefaclor) USP.....250mg

CEFGARD 50mg Drops

Each 1ml of reconstituted suspension contains (Cefaclor) USP.....50mg

PHARMACOLOGY

CEFGARD is well absorbed, following oral administration and achieve peak plasma concentration within 30 to 60 minutes. Average peak serum levels of 7, 13 and 23 mg/l (approx.) have achieved following administration of 250 mg, 500 mg and 1 gm doses respectively in empty stomach, however, when **CEFGARD** is taken with food the peak concentration achieved 50% to 75% of that observed when the drug is administered to fasting subjects and appears 45 to 60 minutes later.

CEFGARD (Cefaclor) serum half-life is 0.6 to 0.9 hr whereas half-life is slightly prolonged in patients with reduced renal function and in the complete absence of renal function the plasma half-life of the intact molecule is 2.3 to 2.8 hrs.

60% to 85% of the drug is excreted unchanged in the urine within 8 hrs. The greater portion is being excreted within first 2 hrs.

MICROBIOLOGY

Cefaclor is a bactericidal cephalosporin. **CEFGARD** (Cefaclor) covers wide range of following gram positive and gram negative bacteria.

- Staphylococci (includes coagulase + ve and - ve and penicillinase producing strains.)
- Streptococcus pyogenes (Group A β - Hemolytic streptococci)
- Streptococcus pneumoniae
- Moraxella (Branhamella) catarrhalis
- Haemophilus influenzae, including β - Lactamase producing strains
- Escherichia coli
- Proteus mirabilis
- Klebsiella spp.
- Citrobacter diversus
- Neisseria gonorrhoeae
- Propionibacteria acnes and Bacteroides spp. (excluding Bacteroides fragilis.)
- Peptococci
- Peptostreptococci.

INDICATIONS

OTITIS MEDIA: Caused by S. pneumoniae, H. influenzae, Staphylococci, S. pyogenes (Group A β - Hemolytic Streptococci) & M. Catarrhalis.

RESPIRATORY INFECTIONS

CEFGARD is highly effective in treating both upper and lower respiratory infections including pneumonia, pharyngitis and tonsillitis caused by S. pneumoniae, H. influenzae, S. pyogenes (Group A β - Hemolytic Streptococci) and M. Catarrhalis.

NOTE: Cefaclor is generally effective in eradication of streptococci from the nasopharynx, but cefaclor efficacy not yet established in treating rheumatic fever or bacterial endocarditis.

URINARY TRACT INFECTIONS

Including pyelonephritis and cystitis caused by E. coli, P. mirabilis, Klebsiella spp. and coagulase negative staphylococci.

SKIN AND SKIN STRUCTURE INFECTIONS

Caused by Staphylococcus aureus and S. pyogenes (Group A β - Hemolytic Streptococci).

- Sinusitis
- Gonococcal urethritis

DOSAGE AND ADMINISTRATION

ADULTS

- The usual adult dosage is 250 mg every 8 hrs. For sinusitis the recommended dosage is 250 mg every 8 hrs. For 10 days.
- In case of severe infections doses may be doubled but total daily dose should not exceed by 4 gm/day.
- For gonococcal urethritis in males and females, a single dose of 3 gm combined with probenecid 1 gm is given.

CHILDREN

- The usual daily dosage for children is 20 mg/kg/day in divided doses are administered 3 times daily.
- In severe infections dose of 40 mg/kg/day in divided doses are recommended with a maximum dosage of 1 gm/day.

Child's Weight (KG)	CEFGARD Suspension			
	20 mg/kg/day		40 mg/kg/day	
	125 mg/5 ml	250 mg/5 ml	125 mg/5 ml	250 mg/5 ml
9	1/2 tsp t.i.d.		1 tsp t.i.d.	1/2 tsp t.i.d.
18	1 tsp t.i.d.	1/2 tsp t.i.d.		1 tsp t.i.d.

B.I.D. DOSAGE

For the treatment of otitis media and pharyngitis, the total dosage may be divided every 12 hrs.

CEFGARD therapeutic dosage should be administered for at least 10 days in case of β - Hemolytic streptococcal infections. In response of the impaired renal function **CEFGARD** may be administered with no change in usual daily dosage.

ADVERSE REACTIONS

HYPERSENSITIVITY: Morbilliform eruptions, pruritus, urticaria and positive coomb's test may rarely occur, serum-sickness like reactions such as erythema multiform, rashes and other skin manifestations accompanied by arthritis/arthralgia with or without fever and differ from classic serum sickness infrequently associated lymphadenopathy and proteinuria, no circulating immune complexes and sequelae of the reactions. Serum-sickness like reactions have been reported more in children than in adults. Sign and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. More severe hypersensitivity reactions such as Stevens Johnsons syndrome, toxic epidermal necrolysis and anaphylaxis reported rarely.

GASTROINTESTINAL: Diarrhoea, nausea and vomiting reported rarely. Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. As with some penicillins and cephalosporins transient hepatitis and cholestatic jaundice have also been reported rarely.

C N S: Reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, hallucinations, and somnolence have been reported.

HEPATIC: Slight elevations of SGOT, SGPT, or alkaline phosphatase values.

HEMATOPOIETIC: Transient lymphocytosis, leukopenia and rarely hemolytic anemia and reversible neutropenia may rarely report as reported with other β -Lactam antibiotics. Rare reports of increased prothrombin time with or without clinical bleeding in patients receiving **CEFGARD** and coumadin concomitantly.

RENAL: Slight elevations in BUN or serum creatinine or abnormal urinalysis.

OTHERS: Very rarely Eosinophilia, Genital pruritus, or Vaginitis thrombocytopenia or reversible interstitial nephritis.

CONTRAINDICATIONS

Hypersensitivity to cephalosporin group of antibiotics.

WARNING: There are clinical and laboratory evidence of partial cross-sensitivity of penicillins and the cephalosporins and there are instances where patients have had reaction, including anaphylaxis, hence cephalosporin antibiotics should be administered with great care in penicillin - sensitive patients.

Pseudomembranous colitis has been reported with virtually all broad spectrum antibiotics and its diagnosis in patients who develop diarrhea in association with the use of antibiotics should be considered. Mild cases usually respond to drug discontinuance alone. Where as appropriate measures should be taken in moderate to severe cases.

PRECAUTIONS

In case of allergic reactions, the drug should be discontinued and if necessary, patient should be treated with appropriate agents, e.g. pressor amines, antihistamines or corticosteroides. Careful observation of patient is essential if super infection occur during therapy and appropriate measures should be taken.

CEFGARD should be administered very carefully in the presence of markedly impaired renal function. A false positive reaction for glucose in urine may occur, as a result of **CEFGARD** administration. Broad spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease particularly colitis.

Positive direct coomb's test have been reported during treatment with the cephalosporin. In hematologic studies or in transfusion/cross-matching procedures it should be recognised that a positive coomb's test may be due to the drug.

USAGE IN PREGNANCY

This drug should be used during pregnancy, only if clearly needed, there are no adequate and well-controlled studies in pregnant women. However reproduction studies in mice/rats or ferrets have revealed no evidence of impaired fertility or harm to fetus due to **CEFGARD** when administered at doses 12 times and 3 times (respectively) more than the maximum human dose.

USAGE DURING LACTATION

Caution should be exercised when **CEFGARD** is administered to a lactating mother. The effect of drug on nursing mother is not known. However small amount of cefaclor have been detected in mother's milk following administration of drug.

USAGE IN CHILDREN

Safety and efficacy of cefaclor have not been established in infants less than one month.

OVER-DOSAGE

Signs and symptoms: An over dose of cefaclor may include, nausea, vomiting, epigastric distress and diarrhoea. The severities of symptoms are dose related.

TREATMENTS

Multiple drug overdoses, interaction among drugs and unusual drug kinetics should also be considered while managing over dosage. Unless cefaclor dose are 5-times more than the normal dose, gastrointestinal decontamination will not be necessary to protect the patient's airway and support, ventilation and perfusion. Monitor and maintain within acceptable limits the patient's vital signs, blood gases, serum electrolytes. In many cases, activated charcoal is more effective than emesis or lavage, consider, charcoal instead of or in addition to gastric emptying.

DIRECTIONS FOR RECONSTITUTION

60ml SUSPENSION (125mg/5ml & 250mg/5ml) WHEN MIXED

Tap the bottle several times to loose the powder. Add 20ml of previously boiled & cooled water using enclosed cup and shake well. Again add 20ml water with the cup & shake well to make 60ml suspension.

15ml SUSPENSION (125mg/5ml & 250mg/5ml) WHEN MIXED

Add a small quantity of boiled & cooled water to the powder in the bottle and shake well, then add water up to the upper mark on the bottle and shake well.

15ml PAEDIATRIC DROPS (50mg/ml) WHEN MIXED

Add a small quantity of boiled & cooled water to the powder in the bottle and shake well, then add water up to the upper mark on the bottle and shake well.

5ml PAEDIATRIC DROPS (50mg/ml) WHEN MIXED

Add a small quantity of boiled & cooled water to the powder in the bottle and shake well, then add water up to the lower mark on the bottle and shake well.

INSTRUCTIONS

Store at 15-30°C. Protect from heat, light & moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

Note: When mixed, store in a refrigerator and use within 14 days.

PRESENTATION

CEFGARD 250mg & 500mg CAPSULES:

Available in packing of 12 capsules.

CEFGARD SUSPENSION: 125mg/5ml (in orange flavor) 60ml (after reconstitution)

CEFGARD FORTE: 250mg/5ml (in orange flavor) 60ml (after reconstitution)

CEFGARD Drops: 50mg/ml (in orange flavor) 15ml (after reconstitution)

سیف گارڈ / سیپول / سیپین / ڈرائس (سیف گارڈ / سیپول / سیپین / ڈرائس)

60 لیٹر سیپین تیار کرنے کا طریقہ: (125mg/5ml, 250mg/5ml)

سیپین بنانے کے لیے بول کا اچھی طرح ملائے تاکہ تمام پاؤڈر بکھیر جائے۔ اب ڈبے میں موجود کپ سے تپ 20 کر لیٹر پیپل سے اُٹھا دیا جائیگا ڈائلس اور درجن کی طرح ملائیں۔ ہرگز 20 لیٹر لیٹر پانی ڈائلس اور اچھی طرح ملائیں تاکہ 60 لیٹر سیپین تیار ہو جائے۔

15 لیٹر سیپین تیار کرنے کا طریقہ: (125mg/5ml, 250mg/5ml)

بول میں تھوڑا سا آب آگیا ہوا غصہ پانی ڈائلس اور درجن لگا کر اچھی طرح ملائیں۔ اب بول پر سنبے اوپر والے نشان کے مطابق اُٹھا دیا ہوا غصہ پانی ڈائلس اور درجن لگا کر اچھی طرح ملائیں۔

15 لیٹر ڈرائس تیار کرنے کا طریقہ: (50mg/ml)

بول میں تھوڑا سا آب آگیا ہوا غصہ پانی ڈائلس اور درجن لگا کر اچھی طرح ملائیں۔ اب بول پر سنبے اوپر والے نشان کے مطابق اُٹھا دیا ہوا غصہ پانی ڈائلس اور درجن لگا کر اچھی طرح ملائیں۔

5 لیٹر ڈرائس تیار کرنے کا طریقہ: (50mg/ml)

بول میں تھوڑا سا آب آگیا ہوا غصہ پانی ڈائلس اور درجن لگا کر اچھی طرح ملائیں۔ اب بول پر سنبے نیچے والے نشان کے مطابق اُٹھا دیا ہوا غصہ پانی ڈائلس اور درجن لگا کر اچھی طرح ملائیں۔

ہدایات: دو کو 15 سے 30 ڈگری سنٹی گریڈ پر رکھیں۔ گرمی، روشنی اور دھوپ سے بچائیں۔ تمام دوا دیکھیں بچوں کی ہتھیلی سے ڈور رکھیں۔ صرف مختصر ڈاکٹر کے نسخہ پر فروخت کریں۔

نوٹ: تیار شدہ دوا کو ریفریجریٹر میں رکھیں اور 14 دن کے اندر استعمال کریں۔



Manufactured by:
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