Bosch

For Healthcare Professionals only

Cefalor®

(Cefaclor)

Capsules, Suspension and Drops

سیفالور کیپسولز، سسپنشن اور ڈراپس

(سیفاکلور)

QUALITATIVE AND QUANTITATIVE COMPOSITION
Cefalor 125mg/5mL Suspension
Each 5mL contains:
Cefaclor USP…. 125mg as Cefaclor Monohydrate
(Product Specs.: USP)

Cefalor 250mg/5mL Suspension
Each 5mL contains:
Cefaclor USP…. 250mg as Cefaclor Monohydrate
(Product Specs.: USP)

Cefalor 50mg/mL Drops
Each mL contains
Cefaclor USP …. 50mg as Cefaclor Monohydrate
(Product Specs.: USP)

Cefalor 250mg Capsules
Each capsule contains:
Cefaclor USP …. 250mg as Cefaclor Monohydrate
(Product Specs.: USP)

Cefalor 500mg Capsules
Each capsule contains:
Cefaclor USP …. 500mg as Cefaclor Monohydrate
(Product Specs.: USP)

PHARMACEUTICAL FORM
Capsules, Granules for Oral Suspension and drops

CLINICAL PARTICULARS
Therapeutic indications
Cefalor is indicated for the treatment of the following infections due to susceptible micro-organisms:
- Respiratory tract infections, including pneumonia, bronchitis, exacerbations of chronic bronchitis, pharyngitis and tonsillitis, and as part of the management of sinusitis.
- Generally effective in the eradication of streptococci from the nasopharynx
- Otitis media
- Skin and soft tissue infections
- Urinary tract infections, including pyelonephritis and cystitis. Cefalor has been found to be effective in both acute and chronic urinary tract infections.

Posology and Method of Administration
Posology
Pediatric population:
The usual recommended daily dosage for children is 20mg/kg/day in divided doses every eight hours, as indicated. For bronchitis and pneumonia, the dosage is 20mg/kg/day in divided doses administered 3 times daily. For otitis media and pharyngitis, the total daily dosage may be divided and administered every 12 hours. Safety and efficacy have not been established for use in infants aged less than one month.

Adults: The usual adult dosage is 250mg every eight hours. For more severe infections or those caused by less susceptible organisms, doses may be doubled. Doses of 4g per day have been administered safely to normal subjects for 28 days, but the total daily dosage should not exceed this amount.

Patients with impaired renal function:
Cefalor may be administered in the presence of impaired renal function. Under such conditions, dosage is unchanged.

Cefalor should be administered with caution in the presence of markedly impaired renal function. Since the half-life of cefaclor in anuric patients is 2.3 to 2.8 hours (compared to 0.6 to 0.9 hours), dosage adjustments for patients with moderate or severe renal impairment are not usually required.

Patients undergoing hemodialysis:
Hemodialysis shortens serum half-life by 25-30%. In patients undergoing regular hemodialysis, a loading dose of 250mg-1g administered prior to dialysis and a therapeutic dose of 250-500mg every six to eight hours maintained during intradialytic periods is recommended.

The elderly: As for adults.

Cefalor Suspension

	125mg/5mL	250mg/5mL
<1 year (9kg)	2.5mL tid	
1-5 years (9-18kg)	5.0mL tid	
Over 5 years		5.0mL tid

In more serious infections, otitis media, sinusitis and infections caused by less susceptible organisms, 40mg/kg/day in divided doses is recommended, up to a daily maximum of 1g.

In the treatment of beta-hemolytic streptococcal infections, therapy should be continued for at least 10 days.

Method of administration
Cefalor is administered orally.

Contraindications
Hypersensitivity to the active substance, any cephalosporins

Special warnings and precautions for use
Warnings
Before instituting therapy with cefaclor, every effort should be made to determine whether the patient has had previous hypersensitivity reactions to cefaclor, cephalosporins, penicillins or other drugs. Cefaclor should be given cautiously to penicillin-sensitive patients, because cross-hypersensitivity, including anaphylaxis among beta-lactam antibiotics has been clearly documented.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose – isomaltase insufficiency should not take this medicine.

If an allergic reaction to cefaclor occurs, the drug should be discontinued and the patient treated with the appropriate agents.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics, including macrolides, semi-synthetic penicillins and cephalosporins. Mild cases usually respond to drug discontinuance alone. In moderate to severe cases, appropriate measures should be taken.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefaclor and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile.* CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Precautions
Reports of neurotoxicity in association with cephalosporin treatment. Symptoms may include encephalopathy, myoclonus and seizures. Elderly patients, patients with severe renal impairment or central nervous system disorders are particularly at risk.

Cefaclor should be administered with caution in the presence of markedly impaired renal function. Since the half-life of cefaclor in anuric patients is 2.3 to 2.8 hours (compared to 0.6-0.9 hours), dosage adjustments for patients with moderate or severe renal impairment are not usually required. If cefaclor associated neurotoxicity is suspected, discontinuation of cefaclor should be considered.

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastro- intestinal disease, particularly colitis.

Prolonged use of cefaclor may result in the overgrowth of non-susceptible organisms. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests reported during treatment with the cephalosporin antibiotics. A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets.

This medicinal product contains less than 1 mmol sodium (23 mg) per 5mL, that is to say essentially 'sodium-free'

Interaction with other medicinal products and other forms of interaction
Increased prothrombin time, with or without clinical bleeding, in patients receiving cefaclor and warfarin concomitantly. It is recommended that in such patients, regular monitoring of prothrombin time should be considered, with adjustment of dosage if necessary.
The renal excretion of cefaclor is inhibited by probenecid.

Fertility, Pregnancy and lactation
Pregnancy: No evidence of impaired fertility or teratogenicity. Caution should be exercised when prescribing for the pregnant patient.

Lactation: The effect on nursing infants is not known, caution should be exercised when cefaclor is administered to a nursing woman.

Effects on ability to drive and use machines
Cefaclor has no known influence on the ability to drive and use machines

Undesirable Effects
Gastro-intestinal:
The most frequent side-effect has been diarrhea. It is rarely severe enough to warrant cessation of therapy. Colitis, including rare instances of pseudomembranous colitis. Nausea and vomiting have also occurred.

Hypersensitivity: Allergic reactions such as morbilliform eruptions, pruritus and urticaria have been observed. These reactions usually subside upon discontinuation of therapy. Serum sickness-like reactions (erythema multiforme minor, rashes or other skin manifestations accompanied by arthritis/arthralgia, with or without fever) may occur.

Lymphadenopathy and proteinuria are infrequent, there are no circulating immune complexes and no evidence of sequelae. Signs and symptoms usually occur a few days after initiation of therapy and usually subside within a few days of cessation of therapy. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Anaphylaxis may be more common in patients with a history of penicillin allergy. Anaphylactic events may present as solitary symptoms, including angioedema, asthenia, edema (including face and limbs), dyspnea, paraesthesias, syncope, or vasodilatation. Rarely, hypersensitivity symptoms may persist for several months.

Hematological: Eosinophilia, positive Coombs' tests and, rarely, thrombocytopenia. Transient lymphocytosis, leucopenia and, rarely, hemolytic anemia, aplastic anemia, agranulocytosis and reversible neutropenia of possible clinical significance.

Hepatic: Transient hepatitis and cholestatic jaundice have been reported rarely, slight elevations in AST, ALT or alkaline phosphatase values.
Renal: Reversible interstitial nephritis has occurred rarely, also slight elevations in blood urea or serum creatinine or abnormal urinalysis.

Central Nervous System: Reversible hyperactivity, agitation, nervousness, insomnia, confusion, hypertonia, dizziness, hallucinations and somnolence have been reported rarely. There have been reports of neurological sequelae including tremor, myoclonia, convulsions, encephalopathy with drugs belonging to the class of cephalosporins.

Miscellaneous: Genital pruritus, vaginitis and vaginal moniliasis.

Overdose
Gastro- intestinal decontamination will not be necessary unless 5 times the normal total daily dose has been ingested, General management may consist of supportive therapy.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: Second-generation cephalosporin antibiotics ATC code: J01DC04

Mechanism of Action
Cefaclor is active against the following organisms:
- Alpha- and beta-hemolytic streptococci
- *Staphylococci,* including coagulase-positive, coagulase-negative and penicillinase producing strains
- *Streptococcus pneumonia,*
- *Streptococcus pyogenes* (group A beta-hemolytic streptococci)
- *Branhamella catarrhalis*
- *Escherichia coli*
- *Proteus mirabilis*
- *Klebsiella species*
- *Haemophilus influenza*, including ampicillin-resistant strains

Cefaclor has no activity against *Pseudomonas* species or *Acinetobacter* species. Methicillin-resistant staphylococci and most strains of enterococci (eg, Str. faecalis) are resistant to cefaclor.
Cefaclor is not active against most strains of *Enterobacter* spp, *Serratia* spp, *Morganella morganii*, *Proteus vulgaris* and *Providencia rettgeri*.

Pharmacokinetic properties

Absorption

Cefaclor is well absorbed after oral administration to fasting subjects. Total absorption is the same whether the drug is given with or without food; however, when it is taken with food, the peak concentration achieved is 50-75% of that observed when the drug is administered to fasting subjects and generally appears from ¾ to one hour later.

Linearity

Following administration of 250mg, 500mg and 1g doses to fasting subjects, average peak serum levels of approximately 7, 13 and 23mg/L respectively were obtained within 30 - 60 minutes.

Biotransformation and Elimination

Approximately 60 - 85% of the drug is excreted unchanged in the urine within eight hours. The serum half-life in normal subjects is 0.6 - 0.9 hours. In patients with reduced renal function, the serum half-life of cefaclor is slightly prolonged. In those with complete absence of renal function, the plasma half-life is 2.3 - 2.8 hours. Excretion pathways in patients with markedly impaired renal function have not been determined. Hemodialysis shortens the half- life by 25 - 30%.

Pediatric Use

Safety and effectiveness of this product for use in infants less than 1 month of age have not been established.

Geriatric Use

This drug is substantially excreted by the kidney and the risk of toxic reactions may be greater in patients with impaired renal function. Elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

PHARMACEUTICAL PROPERTIES

Incompatibilities

None known

Shelf Life

Cefalor Capsules : 03 years
Cefalor Suspension: 02 years
Cefalor Drops: 02 years

Direction for Reconstitution:

Please refer to pack

Special precautions for storage

Protect from heat, sunlight and moisture.
Store at room temperature (15°C - 30°C).
Once reconstituted the suspension should be stored in a refrigerator (2°C-8°C) and used within 14 days.
Do not take if seal is broken.
Close the cap properly after use.
Keep out of the reach of children.
The expiration date refers to the product correctly stored at required condition.
To be sold on the prescription of a registered medical practitioner only.

Nature and contents of container / Presentation

Capsules:

Cefalor 250mg Capsules: Cold form & Cold Seal Blister, Pack of 12 Capsules.
Cefalor 500mg Capsules: Cold form & Cold Seal Blister, Pack of 12 Capsules.

Suspension:

Cefalor 125mg/5mL (60mL): Pack contains Dry Granules for 60mL suspension (after reconstitution) in plastic bottle.
Cefalor 250mg/5mL (60mL): Pack contains Dry Granules for 60mL suspension (after reconstitution) in plastic bottle.

Drops:

Cefalor 50mg/mL Drops (15mL): Pack contains Dry Granules for 15mL Drops (After reconstitution) in plastic bottle.

REGISTRATION HOLDER / MARKETING AUTHORIZATION HOLDER

Head office:

Bosch Pharmaceuticals (Pvt.) Ltd.,
8, Modern Society, Tipu Sultan Road, Karachi - Pakistan

MANUFACTURER

Bosch Pharmaceuticals (Pvt,) Ltd.
221-223, Sector 23, Korangi Industrial Area, Karachi - Pakistan

REGISTRATION / MARKETING AUTHORIZATION NUMBER

Cefalor 125mg/5mL Suspension - 015917
Cefalor 250mg/5mL Suspension - 015918
Cefalor 50mg/mL Drops - 034368
Cefalor 250mg Capsules - 015915
Cefalor 500mg Capsules – 015916

DATE FROM WHICH MARKETING IS AUTHORIZED/RENEWAL OF THE AUTHORIZATION

Cefalor 125mg/5mL Suspension: 15-11-1995/14-11-2020
Cefalor 250mg/5mL Suspension: 15-11-1995/14-11-2020
Cefalor 50mg/mL Drops: 19-11-2004/18-11-2019
Cefalor 250mg Capsules: 15-11-1995/14-11-2020
Cefalor 500mg Capsules: 15-11-1995/14-11-2020

DATE OF REVISION OF THE TEXT:

18-07-2024

دوا تیار کرنے کا طریقہ :
ڈبے پر ملاحظہ فرمائیں
ہدایات:
دھوپ، گرمی اور نمی سے محفوظ کمرے کے درجہ حرارت (۱۵۔۳۰ ڈگری سینٹی گریڈ) پر رکھیں۔
احتیاط: تیار شدہ سسپنشن ریفریجریٹر (۲۔۸) ڈگری سینٹی گریڈ میں رکھیں اور ۱۴ دن کے اندر استعمال کریں۔ کھلی سیل والی بوتل نہ لیں۔
استعمال کے بعد ڈھکن کو اچھی طرح بند رکھیں۔
بچوں کی پہنچ سے دُور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

PK113 1872401

Manufactured by:
Bosch Pharmaceuticals (Pvt.) Ltd.
221-223, Sector 23, Korangi Industrial Area,
Karachi - Pakistan

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Capsules, Suspension and Drops

سیفالور

(سیفاکلور)

کیپسولز، سسپنشن اور ڈراپس

FIRST & ONLY CERTIFIED HALAAL

PHARMACEUTICAL COMPANY