Bosch

For Medical Professional only

# Cefalor®

(Cefaclor)

Capsules / Suspension / Drops

# سیفالور کیپسولز/سسپنشن/ڈراپس

(سیفاکلور)

**DESCRIPTION:**
Cefalor (Cefaclor, USP) is a semisynthetic cephalosporin antibiotic for oral administration. It is chemically designated as 3-chloro-7-D-(2-phenylglycinamido)-3-cephem-4-carboxylic acid monohydrate. The chemical formula for Cefaclor is $C_{15}H_{14}ClN_3O_4S.H_2O$ and the molecular weight is 385.82.

**COMPOSITION:**
Cefalor 250mg Capsule:
Each Capsules Contains: Cefaclor U.S.P. ... 250mg as Cefaclor Monohydrate (Product Specs.: U.S.P.)

Cefalor 500mg Capsule:
Each Capsules Contains: Cefaclor U.S.P. ... 500mg as Cefaclor Monohydrate (Product Specs.: U.S.P.)

Cefalor 125mg/5ml Suspension:
Each 5ml Contains: Cefaclor U.S.P. .....125mg as Cefaclor Monohydrate (Product Specs. U.S.P.)

Cefalor 250mg/5ml Suspension:
Each 5ml Contains: Cefaclor U.S.P. .....250mg as Cefaclor Monohydrate (Product Specs. U.S.P.)

Cefalor 50mg/ml Drops:
Each ml Contains: Cefaclor U.S.P. ..... 50mg as Cefaclor Monohydrate (Product Specs. U.S.P.)

**CLINICAL PHARMACOLOGY:**
**Pharmacodynamic Properties:**
**Pharmacotherapeutic group:** Second-generation cephalosporin antibiotics, ATC code: J01DC04.

**Microbiology:**
Cefaclor is active against the following organisms in vitro:
Alpha- and beta-haemolytic streptococci
Staphylococci; including coagulase-positive, coagulase-negative and penicillinase-producing strains
Streptococcus pneumoniae
Streptococcus pyogenes (group A beta-haemolytic streptococci)
Branhamella catarrhalis
Escherichia coli
Proteus mirabilis
Klebsiella species
Haemophilus influenzae, 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 3/4 to one hour later. Following administration of 250mg, 500mg and 1G doses to fasting subjects, average peak serum levels of approximately 7, 13 and 23 mg/L respectively were obtained within 30 - 60 minutes.
Following administration of 375mg, 500mg and 750mg tablets to fed subjects, average peak serum concentrations of 4, 8 and 11 µg/ml respectively, were obtained within 2.5 to 3 hours. No drug accumulation was noted when this was given twice daily.

**Metabolism & Elimination:**
Approximately 60 - 85% of the drug is excreted unchanged in the urine within eight hours, the greater portion being excreted within the first two hours. During the eight hour period, peak urine concentrations following the 250mg, 500mg and 1gm doses were approximately 600, 900 and 1,900 mg/L respectively. 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 of the intact molecule is 2.3 - 2.8 hours.

**SPECIFIC POPULATIONS**
**Renal impairment**
Excretion pathways in patients with markedly impaired renal function have not been determined. Haemodialysis shortens the half-life by 25 - 30%.

**Elderly:**
Elderly subjects with normal, mildly diminished renal function, do not require dosage adjustment, since higher peak plasma concentrations and AUC had no apparent clinical significance.

**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.
- 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.
- Cefaclor is generally effective in the eradication of streptococci from the nasopharynx.

**DOSAGE AND ADMINISTRATION:**

**Adults & Elderly:**

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.
Pharyngitis, tonsillitis, skin and skin structure infections: 375mg twice daily.
Lower urinary tract infections: 375mg twice daily or 500mg once daily.
Bronchitis: 375mg or 500mg twice daily
Pneumonia: 750mg twice daily.

**Paediatrics**

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.

| **Suspension** | | |
|---|---|---|
| | 125mg/5ml | 250mg/5ml |
| <1 year (9kg) | 2.5ml t.i.d. | |
| 1-5 years (9kg-18kg) | 5.0ml t.i.d. | |
| Over 5 years | | 5.0ml t.i.d. |

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-haemolytic streptococcal infections, therapy should be continued for at least 10 days.

**Patients with Renal Impairment:**

Cefalor may be administered in the presence of impaired renal function. Under such conditions dosage is usually unchanged.

**Patients undergoing haemodialysis:**

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

**Method of Administration:**

Cefalor is administered orally. Absorption is enhanced by administration with food. The tablets should not be cut, crushed, or chewed.

**CONTRAINDICATIONS:**

Hypersensitivity to the active substance, any cephalosporins or to any of the excipients.

**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. It is important, therefore, to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening. Mild cases usually respond to drug discontinuance alone. In moderate to severe cases, appropriate measures should be taken.

**PRECAUTIONS:**

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 in normal subjects), dosage adjustments for patients with moderate or severe renal impairment are not usually required. Clinical experience with cefaclor under such conditions is limited; therefore, careful clinical observation and laboratory studies should be made.

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 have been reported during treatment with the cephalosporin antibiotics. In haematological studies or in transfusion cross-matching procedures, when anti-globulin tests are performed on the minor side, or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognised that a positive Coombs' test may be due to the drug.

A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets.

**DRUG INTERACTIONS:**

There have been rare reports of 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.

The extent of absorption is diminished if magnesium hydroxide or aluminium hydroxide containing antacids are taken within 1 hour of administration. H2 blockers do not alter either the rate or extent of absorption.

**ADVERSE EFFECTS:**

*Gastro-intestinal:* The most frequent side-effect has been diarrhoea. It is rarely severe enough to warrant cessation of therapy. Colitis, including rare instances

of pseudomembranous colitis, has been reported. 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) have been reported. Lymphadenopathy and proteinuria are infrequent, there are no circulating immune complexes and no evidence of sequelae. Occasionally, solitary symptoms may occur, but do not represent a serum sickness-like reaction. Serum sickness-like reactions are apparently due to hypersensitivity and have usually occurred during or following a second (or subsequent) course of therapy with cefaclor. Such reactions have been reported more frequently in children than in adults. 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. No serious sequelae have been reported. There are rare reports of erythema multiforme major (Stevens-Johnson syndrome), toxic epidermal necrolysis, and anaphylaxis. Anaphylaxis may be more common in patients with a history of penicillin allergy. Anaphylactoid events may present as solitary symptoms, including angioedema, asthenia, oedema (including face and limbs), dyspnoea, paraesthesias, syncope, or vasodilatation. Rarely, hypersensitivity symptoms may persist for several months.

*Haematological:* Eosinophilia, positive Coombs' tests and, rarely, thrombocytopenia. Transient lymphocytosis, leucopenia and, rarely, haemolytic anaemia, aplastic anaemia, agranulocytosis and reversible neutropenia of possible clinical significance. See 'Interactions with other Medicaments and other forms of Interaction'.

*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.

*Miscellaneous:* Genital pruritus, vaginitis and vaginal moniliasis.

**USE IN PREGNANCY AND LACTATION:**
**Pregnancy:**
Caution should be exercised when prescribing for the pregnant patient and should be used during pregnancy only if clearly needed.

**Lactation:**
Small amounts of cefaclor have been detected in breast milk following administration of single 500mg doses. Average levels of about 0.2 µg/ml or less were detected up to 5 hours later. Trace amounts were detected at one hour. As the effect on nursing infants is not known, caution should be exercised when cefaclor is administered to a nursing woman.

**OVERDOSE:**
Unless 5 times the normal total daily dose has been ingested, gastro-intestinal decontamination will not be necessary.

General management may consist of supportive therapy. Consider activated charcoal instead of, or in addition to, gastric emptying.

Forced diuresis, peritoneal dialysis, haemodialysis or charcoal haemoperfusion have not been established as beneficial.

**SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING:**
Store at room temperature (15-30°C). Keep containers tightly closed and protect from light. After reconstitution, the suspension should be stored in a refrigerator (2-8°C) and be used within 14 days.

**Shelf Life:**
Capsules 03 Years
Suspention/Drops: 02 Years

**STORAGE & INSTRUCTIONS:**
Protect from heat, sunlight and moisture.
Store at room temperature (15°C - 30°C).
Do not take if seal is broken.
Close the bottle properly after use.
Keep out of the reach of the children.
The expiration date refer to the product correctly stored at required condition.
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

**PRESENTATION:**
**Capsules:**
Cefalor 250mg: Blister pack of 12's capsules.
Cefalor 500mg: Blister pack of 2x6's capsules.
**Suspension:**
Cefalor 125mg/5ml (60ml): Pack contains Dry Granules for 60ml suspension (After reconstitution).
Cefalor 250mg/5ml (60ml): Pack contains Dry Granules for 60ml suspension (After reconstitution).
**Drops:**
Cefalor Drops 50mg/ml (15ml): Pack contains Dry Granules for 15ml Drops (After reconstitution).

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دھوپ گرمی اور نمی سے محفوظ کمرے کے درجہ حرارت (۱۵۔۳۰ ڈگری سینٹی گریڈ) پر رکھیں۔

سسپنشن: 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۔

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