Clobac®

Cefaclor

Description

Cefaclor (**Clobac®**) is a semisynthetic second-generation oral cephalosporin. It is active against the following organisms *In Vitro*: Aerobes, Gram-positive: *Streptococcus pneumoniae*, *Streptococcus pyogenes* (Group A beta-haemolytic *Streptococci*) and *Staphylococci*. Aerobes, Gram-negative: *Moraxella catarrhalis*, *Haemophilus influenzae*, *Escherichia coli*, *Proteus mirabilis*, *Klebsiella* sp., *Citobacter diversus* and *Neisseria gonorrhoeae*. Anaerobes: *Propionibacteria acnes*, Bacteroides sp. (excluding *Bacteroides fragilis*), *Peptococci* and *Peptostreptococcus* sp.

Mode of action

In vitro tests demonstrate that the bactericidal action of Cefaclor results from inhibition of cell-wall synthesis.

Pharmacokinetics

Cefaclor is well absorbed after oral administration, whether taken with food or while fasting. The peak concentration achieved is 50-75% and generally appears from 45 to 60 minutes later. About 25% of cefaclor is bound to plasma proteins. Cefaclor is widely distributed in the body with bactericidal concentrations achieved in middle ear fluid, sinus drainage and bronchial secretions. The serum half-life in normal subjects is 0.6 to 0.9 hour. Approximately 60-85% of the medicine is excreted unchanged in the urine.

Composition

Clobac® Powder for Suspension: After reconstitution, Each 5 ml reconstituted suspension contains Cefaclor Monohydrate USP 131.25 mg equivalent to Cefaclor 125 mg.
Clobac® Paediatric Drops: After reconstitution, Each ml reconstituted suspension contains Cefaclor Monohydrate USP 105 mg equivalent to Cefaclor 100 mg.

Indications

(a) Otitis media and sinusitis
(b) Respiratory tract infections, including pneumonia, bronchitis, exacerbations of chronic bronchitis, pharyngitis and tonsillitis.
(c) Skin and soft tissue infections
(d) Urinary tract infections, including pyelonephritis and cystitis.

Dosage & administration

Clobac® is administered orally.
Adults: The usual adult dosage is 250 mg every 8 to 12 hours. For bronchitis and pneumonia, the dosage is 250 mg administered 3 times daily. A dosage of 250 mg administered 3 times daily for l0 days is recommended for sinusitis. For more severe infections, such as pneumonia, or those caused by less susceptible organisms doses may be doubled. For mild to moderate infections of the urinary tract, skin and soft tissues, and upper respiratory tract, a dosage of 250 mg administered 2 times daily may be sufficient.
Children: The usual recommended dosage for children is 20 mg/kg/day in divided doses every 8 hours. The recommended dosages of Suspension & Paediatric drops are:

Age	Recommended dose		Dosage frequency
	Mild to moderate infections	Dosage Severe infections	
Over 1 month	20 mg/kg	40 mg/kg	8 hourly
1 month - 1 year	62.5 mg	125 mg	8 hourly
1 year - 5 years	125 mg	250 mg	8 hourly
Over 5 years	250 mg	500 mg	8 hourly

The maximum dosage for children over one month should not exceed 1gm/day. Safety and efficacy have not been established for use in infants aged less than 1 month.

Contraindications

Cefaclor is contraindicated in patients with known hypersensitivity to cephalosporin group of antibiotics. It is also contraindicated in porphyria.

Side effects

The most frequent adverse effects reported include gastrointestinal effects (nausea, vomiting, and diarrhea) headache and rash. Rarely, Serum sickness-like reactions consisting of erythema multiforme, urticaria accompanied by arthritis, arthralgia, irritability and fever have been reported.

Use in pregnancy & lactation

Caution should be exercised when prescribing for the pregnant or lactating mother.

Precautions

Cefaclor should be administered with caution in the presence of markedly impaired renal function. Dosage adjustments for patients with moderate or severe renal impairment are not usually required.

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.

Overdosage

The symptoms following an overdose of Cefaclor may include nausea, vomiting, epigastric distress, and diarrhea. The severity of the epigastric distress and diarrhea is dose related. Unless 5 times the normal dose of Cefaclor has been ingested, gastrointestinal lavage will not be necessary.

Storage: Store in a cool and dry place, protected from light.

Packaging: Clobac® Powder for Suspension: Each carton contains a bottle having dry powder to reconstitute 100 ml suspension and a spoon.
Clobac® Paediatric Drops: Each carton contains a bottle having dry powder to reconstitute 15 ml paediatric drops, a dropper and a spoon.

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Opsonin Pharma
Ideas for healthcare

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