Abaclor®

Cefaclor

Description

Abaclor® is the preparation of Cefaclor, which is a semisynthetic second generation Cephalosporin antibiotic for oral administration. It is a bactericidal antibiotic act by inhibiting the cell wall synthesis of microorganisms & has greater stability against β-lactamase enzymes.

Indications

Abaclor® is indicated in the treatment of the following infections:

- Respiratory tract infections, including pneumonia, bronchitis, caused by *Streptococcus pneumoniae, Haemophilus influenzae,* and *Streptococcus pyogenes*
- Otitis media caused by *Streptococcus pneumoniae*, *Haemophilus influenzae, Staphylococci*, and *Streptococcus pyogenes*
- Pharyngitis and Tonsillitis, caused by *Streptococcus pyogenes*
- Urinary tract infections, including pyelonephritis and cystitis, caused by *Escherichia coli, Proteus mirabilis, Klebsiella spp*., and coagulase-negative *Staphylococci*
- Skin and skin structure infections caused by *Staphylococcus aureus* and *Streptococcus pyogenes*

Dosage and administration

Abaclor® capsules

- ***Adults*** **:**
  Abaclor® capsule**:** The usual dose is 250 mg every 8 hourly. For severe infections or those caused by less susceptible organisms, doses may be doubled with a maximum dosage of 4 g/day

Note: In case of β-hemolytic Streptococcal infections, therapy should be administered for at least 10 days

Abaclor® powder for suspension & paediatric drops

Children: The usual daily dosage for paediatric patients over 1 month is 20 mg/kg/day in divided doses every 8 hours. In serious infections such as otitis media and infections caused by less susceptible organisms, 40 mg/kg/day are recommended, with a maximum dosage of 1 g/day. Safety and effectiveness of Cefaclor for use in infants less than 1 month of age have not been established.

Age	***Abaclor® powder for susp (125mg/5ml)***	***Abaclor® paediatric (125mg/1.25ml)***
< 1 year (9 kg)	½ tsp three times daily	0.625 ml three times daily
1-5 years (9kg – 18kg)	1 tsp three times daily	1.25 ml three times daily
Over 5 years	2 tsp three times daily	

In renal impairment: Abaclor® may be administered in the presence of impaired renal function. Dose adjustments for patients with moderate or sever renal impairment are not usually required.

In patients undergoing haemodialysis: Haemodialysis shortens serum half-life by 25-30%. In patients undergoing haemodialysis, a predialysis loading dose of 250mg-1g is recommended. A maintaining dose of 250-500mg every 6 hourly during interdialytic period may be used.

Geriatric use: Clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Use in pregnacy & lactation

There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.
Small amounts of Cefaclor have been detected in mother's milk. The effect on nursing infants is not known. Caution should be exercised when Cefaclor is administered to a nursing woman.

Precautions

Prescribing Cefaclor in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Prolonged use of Cefaclor may result in the overgrowth of nonsusceptible organisms. If superinfection occurs during therapy, appropriate measures should be taken.
As with other β-lactam antibiotics, the renal excretion of Cefaclor is inhibited by Probenecid.
Antibiotics, including Cephalosporins, should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Before therapy with Cefaclor is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to Cefaclor, Cephalosporins, Penicillins or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised.
Cefaclor should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Side effects

Gastro-intestinal symptoms may occur include diarrhea, nausea and vomiting in some patients receiving Cefaclor. As with some penicillins and some other Cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely. Fever, abdominal pain, superinfection, renal dysfunction, toxic nephropathy, hemorrhage, elevated LDH and pancytopenia may occur.

Drug interactions

Cefaclor may show a false-positive reaction for glucose in the urine with tests that use Benedict's solution, Fehling's solutions. When Cefaclor and oral anticoagulants were administered concomitantly there have been reports of increased anticoagulant effect and there have been rare reports of increased prothrombin time, with or without clinical bleeding, in patients receiving Cefaclor and anticoagulants (Warfarin) concomitantly. It is recommended that in such patients, regular monitoring of prothrombin time should be considered, with adjustment of dosage if necessary.

Contraindications

Cefaclor is contraindicated in patients with known allergy to the Cephalosporin group of antibiotics.

Overdose

The toxic symptoms following an overdose of Cefaclor may include nausea, vomiting, epigastric distress, and diarrhea.

Preparation of Suspension & Paediatric drops

Abaclor® Powder for Suspension: Shake the bottle well before mixing the water. To prepare 100 ml suspension, add 62.5 ml (12.5 spoonfuls) of boiled & cooled water in two portions and shake till powder is completely mixed with water. The prepared suspension can be used within 7 days if it is stored at room tempature and 14 days if it is kept in refrigerator.

Abaclor® Paediatric Drops: Shake the bottle well before mixing the water. To prepare 15 ml paediatric drops, add 10 ml (2 spoonfuls) of boiled & cooled water in two portions and shake till powder is completely mixed with water. The prepared drops can be used within 7 days if it is stored at room temperature and 14 days if it is kept in refrigerator.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentations

Abaclor® 250mg Capsule	: Each capsule contains Cefaclor monohydrate USP 250mg
Abaclor® 500mg Capsule	: Each capsule contains Cefaclor monohydrate USP 500mg
Abaclor® Powder for Suspension	: Bottle containing powder for preparation of 100ml suspension, after reconstitution each 5 ml contains Cefaclor monohydrate USP 125 mg
Abaclor® Paediatric Drops	: Bottle containing powder for preparation of 15ml drops, after reconstitution each 1.25 ml contains Cefaclor monohydrate USP 125 mg

Package quantities

Abaclor® 250mg Capsule	: Carton of 20 capsules in Alu-Alu Blister
Abaclor® 500mg Capsule	: Carton of 12 capsules in Alu-Alu Blister
Abaclor® Powder for Suspension	: Bottle of 100 ml
Abaclor® Paediatric Drops	: Bottle of 15 ml

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