# Cefaclor
# Ceclobid

℞

250 mg / 5 mL Powder for Oral Suspension
50 mg / mL Powder for Suspension (Pediatric Oral Drops)

**ANTIBACTERIAL**

CYDC

**PRODUCT DESCRIPTION**

Ceclobid 250 mg / 5 mL Powder for Oral Suspension:
Dry powder: Yellow powder, banana odor
Reconstituted Suspension: Color yellow suspension, banana flavor

Ceclobid 50 mg / mL Powder for Suspension (Pediatric Oral Drops):
Dry powder: Pink powder, cherry odor
Reconstituted Suspension: Color pink suspension, cherry flavor

**FORMULATION**

Each 5 mL (1 teaspoonful) of reconstituted suspension contains: Cefaclor (as monohydrate) 250 mg.
Each mL of reconstituted suspension contains: Cefaclor (as monohydrate) 50 mg.

**PHARMACOKINETICS**

Cefaclor is well absorbed from the gastrointestinal tract but plasma concentrations are slightly lower than those achieved with Cephalexin or Cephradine. Doses of 250, 500 and 1000 mg by mouth produce peak plasma concentrations of about 6, 13, 23 ug per mL respectively at 0.5 to 1 hour. The presence of food may delay the absorption of Cefaclor, but the total amount absorbed is unchanged. A plasma half-life of 0.5 to 1 hour has been reported; it may be slightly prolonged in renal failure. About 25% is bound to plasma proteins. It is rapidly excreted by the kidneys; up to 85% of a dose appears unchanged in the urine within 8 hours, the greater part within 2 hours. High concentration of 600, 900 and 1,900 ug per mL have been reported after doses of 250, 500 and 1,000 mg respectively. Probenecid delays excretion. Cefaclor is removed by haemodialysis.

**PHARMACODYNAMICS AND ANTIMICROBIAL ACTION**

Cefaclor is a second generation cephalosporin. Cefaclor is bactericidal, it acts by inhibiting synthesis of bacterial cell wall. It has antimicrobial activity similar to first generation but reported to be more active against Gram-negative bacteria including Escherichia coli, Klebsiella pneumoniae, Neisseria gonorrhoeae, Proteus mirabilis and especially against Haemophilus influenzae. It is active against some beta-lactamase-producing strains of H. influenzae. It may be less resistant to staphylococcal penicillinase than cephalexin or cephradine.

**INDICATIONS**

Cefaclor is a cephalosporin antibiotic administered by mouth similarly to Cefalexin in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

*Lower respiratory tract infections*, including pneumonia, acute bronchitis, acute exacerbations of chronic bronchitis caused by S. pneumoniae, H. influenzae, Staphylococci, S. pyogenes (group A β-hemolytic streptococci), and M. catarrhalis.

*Upper respiratory infections*, including pharyngitis and tonsilitis, caused by S. pyogenes (group A β-hemolytic streptococci), and M. catarrhalis.

*Urinary tract infections*, including pyelonephritis and cystitis, caused by E. coli, P. mirabilis, Klebsiella spp. and coagulase-negative Staphylococci.

Note: Cefaclor has been found to be effective in both acute and chronic urinary tract infections.

*Skin and soft tissue infections* caused by Staphylococcus aureus and S. pyogenes (group A β-hemolytic streptococci).

*Otitis media* caused by S. pneumoniae, H. influenzae, Staphylococci, S. pyogenes (group A β-hemolytic streptococci), and M. catarrhalis.

Cefaclor is classified as a second generation cephalosporin and its greater activity against Haemophilus influenzae makes it more suitable than cephalexin for the treatment of infections such as otitis media.

*Sinusitis*

*Gonococcal urethritis*
Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Cefaclor.

**DOSAGE AND ADMINISTRATION**

POWDER FOR ORAL SUSPENSION

| AGE | DOSE/FREQUENCY |
|---|---|
| Over 1 month of age | 20 mg / kg body weight daily in three divided doses increase if necessary to 40 mg/kg daily but not exceeding a total daily dose of 1 g. |
| 1-5 years | 125 mg three times daily |
| Over 5 years of age | 250 mg three times daily |
| Adolescent and adult | 250 - 500 mg every 8 hours up to 4 g daily |

For bronchitis and pneumonia, the dosage is 250 mg administered three times daily. A dosage of 250 mg administered three times daily for 10 days is recommended for sinusitis. For more severe infections (such as pneumonia) or those caused by less susceptible organisms, doses may be doubled. Doses of 4 g per day have been administered safely to normal subjects for 28 days, but the total daily dosage should not exceed this amount. For the treatment of acute gonococcal urethritis in males and females, a single dose of 3 g combined with 1 g probenecid is given. Or as prescribed by the physician.
For children over 1 month, the usual recommended daily dosage is 20 mg/kg per day in divided doses every 8 hours. For bronchitis and pneumonia, the dosage is 20 mg/kg per day in divided doses administered three times daily. In more serious infections, otitis media and infections caused by less susceptible organisms, 40 mg/kg per day in divided doses are recommended, with a maximum dosage of 1 g per day or as prescribed by the physician.

**DIRECTIONS FOR RECONSTITUTION**

To make a 60 mL suspension, add 38 mL of water to 250 mg/5 mL Cefaclor Powder for Oral Suspension.

To make 20 mL suspension, add 14 mL of water to 50 mg/mL Cefaclor Powder for Suspension (Pediatric Oral Drops).

Shake well until the contents are evenly suspended. The reconstituted suspension is stable for 14 days when refrigerated (2 - 8°C) and 7 days if stored at temperatures not exceeding 30°C.

**CONTRAINDICATIONS**

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

**PRECAUTIONS**
Prolonged use of Cefaclor may result in overgrowth of non-susceptible organisms and as with other broad spectrum antibiotics, pseudomembranous colitis may develop. Cefaclor should not be given to patients who are hypersensitive to it or to other cephalosporins. About 10% of penicillin-sensitive patients may also be allergic to cephalosporins. Great care should be taken if Cefaclor is to be given to such patients. Care is also necessary in patients with known histories of allergy. Cefaclor should be given with caution to patients with renal impairment a dosage reduction may be necessary. Renal and haematological status should be monitored especially during prolonged and high-dose therapy.

**DRUG/LABORATORY TEST INTERACTIONS**
Positive results to the direct Coombs test have been found during treatment with cephalosporins and these can interfere with blood cross matching. The urine of patients being treated with Cefaclor may give false-positive reactions for glucose using copper-reduction reactions.

- The renal excretion of cefaclor and many other cephalosporins, is delayed by probenecid.
- Anticoagulants. UK licensed product information recommends that monitoring of prothrombin time should be considered in patients receiving cefaclor and warfarin after rare reports of increased prothrombin times. It is not known whether this interaction is related to the vitamin K-related hypoprothrombinaemia observed with some cephalosporins, but cefaclor does not contain the sidechain usually implicated in this reaction.

**OVERDOSE AND TREATMENT**
Signs and Symptoms: The toxic symptoms following an overdose of cefaclor may include nausea, vomiting, epigastric distress, and diarrhea. The severity of epigastric distress and the diarrhea are dose related. If other symptoms are present, it is probable that they are secondary to an underlying disease state, an allergic reaction, or the effects of other intoxication.
Treatment: In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.
Unless 5 times the normal dose of cefaclor has been ingested, gastrointestinal decontamination will not be necessary. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying or charcoal.
Forced diuresis, peritoneal dialysis, hemodialysis or charcoal hemoperfusion have not been established as beneficial for an overdose of cefaclor.

**ADVERSE EFFECTS**
The most common are hypersensitivity reactions including skin rashes, urticaria, eosinophilia fever, reactions resembling serum sickness and anaphylaxis.
There may be a positive response to the Coombs test although haemolytic anemia rarely occurs. Neutropenia and thrombocytopenia have occasionally been reported. Agranulocytosis has been associated rarely with some cephalosporins. Acute renal tubular necrosis has followed excessive dosage and has also been associated with its use in older patients or those with pre-existing renal impairment, or with the concomitant administration of nephrotoxic drugs such as aminoglycoside antibiotics. Acute interstitial nephritis is also a possibility as a manifestation of hypersensitivity. Transient increases in liver enzyme values have been reported. Hepatitis and cholestatic jaundice have occurred rarely with some cephalosporins. Convulsions and other signs of CNS toxicity have been associated with high doses, especially in patients with renal failure. Gastrointestinal adverse effects such as nausea, vomiting and diarrhea have been reported rarely. Prolonged use may result in overgrowth of non-susceptible organisms and, as with other broad-spectrum antibiotics, pseudomembranous colitis may develop.

**WARNING**
For 250 mg/5 mL:
This product contains FD & C Yellow #5 (Tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons.

**CAUTION**
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**AVAILABILITY**
Ceclobid 250 mg/5 mL Powder for Oral Suspension - Amber Glass Bottle x 60 mL (Box of 1's)
Ceclobid 50 mg/mL Powder for Suspension (Pediatric Oral Drops) - Amber Glass Bottle x 20 mL w/ Medicine Dropper (Box of 1's)

**STORAGE CONDITION**
Store at temperatures not exceeding 30°C.

**ADR REPORTING STATEMENT**
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek advice from a healthcare professional at the first sign of any adverse drug reaction.

Marketing Authorization Holder
**THE CATHAY YSS DISTRIBUTORS CO., INC.**
2/F Vernida I Condominium, 120 Amorsolo St., Legaspi Village, Makati City

Manufacturer
**EL LABORATORIES, INC.**
109 North Main Ave., Laguna Technopark, Biñan, Laguna

| PRODUCT | REGISTRATION NO. | DATE OF FIRST AUTHORIZATION |
|---|---|---|
| CECLOBID 250 mg / 5 mL POWDER FOR ORAL SUSPENSION | DRP-3873 | 20 March 2012 |
| CECLOBID 50 mg / mL POWDER FOR SUSPENSION (PEDIATRIC ORAL DROPS) | DRP-2101 | 29 December 2009 |

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