

# Cefracef

Cefradine

## COMPOSITION

**Cefracef 250 Capsule:** Each capsule contains Cefradine Monohydrate BP equivalent to Cefradine 250 mg.

**Cefracef 500 Capsule:** Each capsule contains Cefradine Monohydrate BP equivalent to Cefradine 500 mg.

**Cefracef Powder for Suspension:** After reconstitution, each 5 ml suspension contains Cefradine Monohydrate BP equivalent to Cefradine 125 mg.

**Cefracef DS Powder for Suspension:** After reconstitution, each 5 ml suspension contains Cefradine Monohydrate BP equivalent to Cefradine 250 mg.

## PHARMACOLOGY

Cefracef (Cefradine) is a cephalosporin antibiotic used to treat certain infections caused by bacteria, such as pneumonia, ear, nose, throat, skin and urinary tract infections. It is acid stable and rapidly absorbed after oral administration. The presence of food in the gastrointestinal tract delays absorption but does not affect the total amount of Cefradine absorbed. Over 90% of this drug is excreted as unchanged in the urine within six hours.

## INDICATIONS

Cefracef (Cefradine) is indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms:

Respiratory tract infections (e.g. tonsillitis, pharyngitis and lobar pneumonia) caused by group A beta-hemolytic **Streptococci** and **Streptococcus pneumoniae**.

Skin and Skin Structure Infections caused by **Staphylococci** (penicillin-susceptible and penicillin-resistant) and beta-hemolytic **Streptococci**.

Urinary Tract Infections including prostatitis caused by **E. coli**, **Proteus mirabilis**, **Klebsiella species**, and **Enterococci**.

It is also used in Otitis media caused by group A beta-hemolytic **Streptococci**, **Streptococcus pneumoniae**, **Haemophilus influenzae** and **Staphylococci**.

## DOSAGE AND ADMINISTRATION

### Adults:

**Respiratory Tract Infections (other than lobar pneumonia) and Skin and Skin Structure Infections:** The usual dose is 250 mg every 6 hours or 500 mg every 12 hours. For lobar pneumonia, the usual dose is 500 mg every 6 hours or 1 g every 12 hours.

**Uncomplicated Urinary Tract Infections:** The usual dose is 500 mg every 12 hours. In more serious urinary tract infections, including prostatitis, 500 mg every 6 hours or 1 g every 12 hours may be administered.

**Children:** The usual dose in children over 9 months of age is 25 to 50 mg/ kg/ day administered in equally divided doses every 6 or 12 hours. For Otitis media due to **H. influenzae**, doses are from 75 to 100 mg/ kg/ day administered in equally divided doses every 6 or 12 hours, but should not exceed 4 g per day.

**All patients, regardless of age and weight:** Larger doses (up to 1 g q.i.d.) may be given for severe or chronic infections.

## CONTRAINDICATIONS

Cefradine is contraindicated in patients with known hypersensitivity to the cephalosporin group of antibiotics.

## WARNING & PRECAUTION

Care is necessary with known history of allergy. Renal and hematological status should be monitored especially during prolonged and high doses therapy.

## SIDE EFFECTS

As with other cephalosporins, side effects are limited essentially to gastrointestinal disturbances and on occasion to hypersensitivity phenomena, eosinophilia.

## USE IN PREGNANCY & LACTATION

US FDA Pregnancy Category of Cefradine is B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Cefradine has been shown to be excreted in human milk. So, caution should be exercised when Cefradine is administered to a nursing woman.

## USE IN CHILDREN & ADOLESCENTS

Can be used from 9 months of age and older.

## DRUG INTERACTIONS

The concomitant use of Aminoglycosides, Colistin, Polymyxins, Vancomycin, Diuretics (e.g., frusemide, ethacrynic acid) and Probenecid with Cefradine may increase the risk of nephrotoxicity.

## OVERDOSAGE

Overdose symptoms are nausea, vomiting, stomach pain, or diarrhea. In this case, need emergency medical attention.

## STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

## HOW SUPPLIED

**Cefracef 250 Capsule:** Each box contains 30 capsules in Alu-Alu blister pack.

**Cefracef 500 Capsule:** Each box contains 24 capsules in Alu-Alu blister pack.

**Cefracef Powder for Suspension:** Each amber glass bottle contains dry powder to reconstitute 100 ml suspension.

**Cefracef DS Powder for Suspension:** Each amber glass bottle contains dry powder to reconstitute 100 ml suspension.