

# Intracef®

Capsule/ Suspension / DS Suspension / Paediatric Drops

## Description

Intracef contains Cefradine which is a semisynthetic first generation cephalosporin antibiotic that works in a similar way to penicillin by inhibiting bacterial cell wall synthesis. The chemical name of Cefradine is [6R-[6 $\alpha$ , 7 $\beta$ (R\*)]]7-[(Amino-1,4-cyclohexadien-1-yl)-acetyl] amino-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]-oct-2-ene-2-carboxylic acid.

## Indications

Intracef is a broad spectrum bactericidal antibiotic active against both Gram-positive and Gram-negative bacteria. It is also highly active against most strains of penicillinase producing staphylococci.

Intracef is indicated for the treatment of the following infections when caused by susceptible organisms.

- ◆ The upper and lower respiratory tract infections : pharyngitis, sinusitis, otitis media, tonsillitis, laryngo-tracheo-bronchitis, acute and chronic bronchitis, lobar pneumonia
- ◆ Gastrointestinal tract infections
- ◆ Urinary tract infections : cystitis, urethritis, pyelonephritis
- ◆ Skin and soft tissue infections : abscess, cellulitis, furunculosis and impetigo
- ◆ Prophylaxis for surgical procedures associated with high risk of disastrous consequences of infection.

Intracef is also of value where postoperative infections would be disastrous and where patients have a reduced host resistance to bacterial infection. Protection is best ensured by achieving adequate local tissue concentrations at the time of contamination is likely to occur. Thus, Intracef should be administered immediately prior to surgery and continued during the postoperative period.

## Dosage and Administration

Intracef may be given regardless of meals.

*Adults* : For urinary tract infections the usual dose is 500 mg four times daily or 1 g twice daily; severe or chronic infections may require larger dose. Prolonged intensive therapy is needed for complications such as prostatitis and epididymitis. For respiratory tract infections and skin and soft tissue infections the usual dose is 250 mg or 500 mg four times daily or 500 mg or 1g twice daily depending on the severity and site of infection.

*Children* : The usual dose is from 25 to 50 mg/kg/day total, given in two or four equally divided doses.

For otitis media daily dose from 75 to 100 mg/kg body weight in divided doses every 6 to 12 hours are recommended. Maximum dose is 4 g per day.

*Elderly* : There are no specific dosage recommendations or precautions for use in the elderly except as with other drugs to monitor those patients with impaired renal or hepatic function.

*Dosage in renal impairment* : A modified dosage schedule is necessary in patients with decreased renal function. Each patient should be considered individually; the following modified dosage schedule is recommended as a guideline, based on the creatinine clearance (ml/min/1.73m<sup>2</sup>). In adults, the initial loading dose is 750 mg of Intraccef and the maintenance dose is 500 mg at the time intervals listed below :

<b>Creatinine Clearance</b>	<b>Time Interval</b>
More than 20 ml/min	6-12 hours
15-19 ml/min	12-24 hours
10-14 ml/min	24-40 hours
5-9 ml/min	40-50 hours
Less than 5 ml/min	50-70 hours

*Further modification of the dosage schedule may be necessary in children.*

### **Contraindication**

Patients with known hypersensitivity to cephalosporin antibiotics.

### **Precautions**

There is evidence of partial cross allergenicity between penicillins and the cephalosporins. Therefore Cefradine should be used with caution in patients with known hypersensitivity to penicillins.

## **Drug Interactions**

The cephalosporins are potentially nephrotoxic (particularly Cephaloridine) and may enhance the nephrotoxicity of aminoglycoside antibiotics such as Gentamicin and Tobramycin. One should be cautious about the use of any cephalosporin with Furosemide and Ethacrynic acid.

## **Side Effects**

Rarely Cefradine may induce hypersensitivity reaction, nausea, vomiting, diarrhoea, glossitis, heartburn, dizziness, abdominal pain, candidal overgrowth, vaginitis, urticaria, skin rashes, joint pain and oedema. As with other cephalosporins, mild transient eosinophilia, leucopenia and neutropenia, rarely positive direct Coombs' test and pseudomembranous colitis have been reported.

## **Use in Special Population**

*Pregnancy and lactation* : No teratogenicity has been demonstrated in animals, but safety in pregnancy has not been established. Cefradine is excreted in breast milk and should be used with caution in lactating mothers.

## **Commercial Packs**

Intracef® 250 Capsule : Box containing 5 x 10's blister strips. Each capsule contains Cefradine BP 250 mg.

Intracef® 500 Capsule : Box containing 4 x 10's blister strips. Each capsule contains Cefradine BP 500 mg.

Intracef® Suspension : Each amber glass bottle contains dry powder for 100 ml suspension. After reconstitution each 5 ml contains Cefradine BP 125 mg.

Intracef® DS Suspension : Each amber glass bottle contains Cefradine dry powder for oral suspension. After reconstitution, the total volume of suspension will be 100 ml and each 5 ml contains Cefradine BP 250 mg.

Intracef® Paediatric Drops : Each amber glass bottle contains dry powder for 15 ml paediatric drops. After reconstitution each 1.25 ml contains Cefradine BP 125 mg.