Maxcef®

Cefotaxime USP

COMPOSITION
Maxcef ® 250 mg IM/IV injection: Each vial contains Cefotaxime USP 250 mg as Cefotaxime Sodium. Each ampoule contains a solvent of 5 ml water for injection BP.
Maxcef ® 500 mg IM/IV injection: Each vial contains Cefotaxime USP 500 mg as Cefotaxime Sodium. Each ampoule contains a solvent of 10 ml water for injection BP.
Maxcef ® 1gm IM/IV injection: Each vial contains Cefotaxime USP 1 gm as Cefotaxime Sodium. Each ampoule contains a solvent of 10 ml water for injection BP.

PHARMACOLOGY
Following IM administration of a single 500 mg or 1 g dose of **Maxcef** ® to normal volunteers, mean peak serum concentrations of 11.7 and 20.5 mcg/mL respectively were attained within 30 minutes and declined with an elimination half-life of approximately 1 hour. There was a dose-dependent increase in serum levels after the IV administration of 500 mg, 1 g, and 2 g of **Maxcef** ® (38.9, 101.7, and 214.4 mcg/mL respectively) without alteration in the elimination half-life. There is no evidence of accumulation following repetitive IV infusion of 1 g doses every 6 hours for 14 days as there are no alterations of serum or renal clearance. About 60% of the administered dose was recovered from urine during the first 6 hours following the start of the infusion.
Approximately 20-36% of an intravenously administered dose of 14C-cefotaxime is excreted by the kidney as unchanged cefotaxime and 15-25% as the desacetyl derivative, the major metabolite. The desacetyl metabolite has been shown to contribute to the bactericidal activity. Two other urinary metabolites (M2 and M3) account for about 20-25%. They lack bactericidal activity.
A single 50 mg/kg dose of **Maxcef** ® was administered as an intravenous infusion over a 10- to 15-minute period to 29 newborn infants grouped according to birth weight and age. The mean half-life of cefotaxime in infants with lower birth weights (<1500 grams), regardless of age, was longer (4.6 hours) than the mean half-life (3.4 hours) in infants whose birth weight was greater than 1500 grams. Mean serum clearance was also smaller in the lower birth weight infants. Although the differences in mean half-life values are statistically significant for weight, they are not clinically important. Therefore, dosage should be based solely on age.
Additionally, no disulfiram-like reactions were reported in a study conducted in 22 healthy volunteers administered **Maxcef** ® and ethanol.

INDICATION
Maxcef ® (Cefotaxime) is indicated for the treatment of the following infections either before the infecting organism has been identified or when caused by bacteria of established sensitivity:
Septicaemia Respiratory Tract Infections such as acute or chronic bronchitis, bacterial pneumonia, infected bronchiectasis, lung abscess and postoperative chest infections
Urinary Tract Infections such as acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria.
Soft-tissue Infection such as cellulitis, peritonitis and wound infections.
Bone and Joint Infections such as osteomyelitis, septic arthritis.
Obstetric and gynaecological infections: such as pelvic inflammatory disease.
Gonorrhoea particularly when penicillin has failed or is unsuitable.
Other Bacterial Infections: meningitis and other sensitive infections suitable for parenteral antibiotic therapy.
Prophylaxis: The administration of Cefotaxime prophylactically may reduce the incidence of certain post operative infections in patients undergoing surgical procedures that are classified as contaminated or potentially contaminated or in clean operation where infection would have serious effects.

DOSAGE AND ADMINISTRATION
Adults:
The recommended dosage for mild to moderate infections is 1g every 12 hourly. However, dosage may be varied according to the severity of infection, sensitivity of causative organisms and condition of the patient. In severe infections dosage may be increased up to 12 g daily given in 3 or 4 divided doses. For infections caused by sensitive *Pseudomonas spp*. daily doses of greater than 6 g will usually be required.

Children:
The usual dosage range is 100-150 mg/kg/day in 2 to 4 divided doses. However, in very severe infections doses of up to 200 mg/kg/day may be required.

Neonates:
The recommended dosage is 50 mg/kg/day in 2 to 4 divided doses. In severe infections 150-200 mg/kg/day, in divided doses, have been given.

Dosage in gonorrhoea
A single injection of 1 g may be administered intramuscularly or intravenously.

Dosage in renal impairment
Because of extra-renal elimination, it is only necessary to reduce the dosage of Cefotaxime in severe renal failure (GFR<5 ml/min = serum creatinine approximately 751 micromol/litre). After an initial loading dose of 1 g, daily dose should be halved without change in the frequency of dosing. In all other patients, dosage may require further adjustment according to the course of infection and the general condition of the patient.

Direction for reconstitution
For reconstitution purpose add water for injection as per the following chart:

Route	250 mg	500 mg	1 gm
IM	2 ml	2 ml	3 ml
IV	2-5 ml	2-10 ml	4-10 ml

CONTRAINDICATION AND PRECAUTION
Maxcef ® (Cefotaxime) is contraindicated in patients who have shown hypersensitivity to cefotaxime or the cephalosporin group of antibiotics.
Maxcef ® (Cefotaxime) should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. Because high and prolonged antibiotic concentrations can occur from usual doses in patients with transient or persistent reduction of urinary output because of renal insufficiency, the total daily dosage should be reduced when Cefotaxime is administered to such patients. Continued dosage should be determined by degree of renal impairment, severity of infection, and susceptibility of the causative organism. There is no clinical evidence supporting the necessity of changing the dosage of Cefotaxime in patients with even profound renal dysfunction.

SIDE EFFECT
Adverse reactions to Cefotaxime have occurred relatively infrequently and have generally been mild and transient. Effects reported include candidiasis, rashes, fever, transient rises in liver transaminase and/or alkaline phosphatase and diarrhoea. As with all cephalosporins, pseudomembranous colitis may rarely occur during treatment. If this occurs the drug should be stopped and specific treatment instituted.
As with other cephalosporins, changes in renal function have been rarely observed with high doses of Cefotaxime. Administration of high doses of cephalosporins particularly in patients with renal insufficiency may result in encephalopathy.
Hypersensitivity reactions have been reported, these include skin rashes, drug fever and very rarely anaphylaxis.

DRUG INTERACTION
Increased nephrotoxicity has been reported following concomitant administration of cephalosporins and aminoglycoside antibiotics.

PREGNANCY AND LACTATION
Although studies in animals have not shown any adverse effect on the developing foetus, the safety of Cefotaxime in human pregnancy has not been established. Consequently, Cefotaxime should not be administered during pregnancy especially during first trimester, without carefully weighing the expected benefit against possible risks. Cefotaxime is excreted in the milk.

STORAGE
Store below 25°C. Protect from light and moisture. Keep out of children's reach.

HOW SUPPLIED
Maxcef ® 250 IM/IV injection: Vial contains Cefotaxime USP 250 mg as Cefotaxime Sodium accompanied by a solvent ampoule of 5 ml water for injection BP.
Maxcef ® 500 mg IM/IV injection: Vial contains Cefotaxime USP 500 mg as Cefotaxime Sodium accompanied by a solvent ampoule of 10 ml water for injection BP.
Maxcef ® 1 gm IM/IV injection: Vial contains Cefotaxime USP 1 gm as Cefotaxime Sodium accompanied by a solvent ampoule of 10 ml water for injection BP.

SQUARE