DOSAGE AND ADMINISTRATION
Cefuroxime should be administered by the I.M. or I.V. route.
Dosage changes according to the degree of severity and to the doctor’s judgment.
General dosage recommendations:
• **Infants and children**: 30-100 mg/kg/day in 3-4 divided doses. A dose of 60 mg/kg/day will be appropriate for most infections.
• **Adults**: many infections will respond to 750 mg three times daily by I.M. or I.V. injection. For more severe infections, this dose should be increased to 1.5 g three times daily I.V. The frequency may be increased to 6-hourly if necessary, giving total daily doses of 3 to 6 g.
**Gonorrhoea**: 1.5 g as a single dose or 2×750 mg injections into different sites, e.g. each buttock.
**Meningitis**: cefuroxime sodium is suitable for sole therapy of bacterial meningitis due to sensitive strains.
• **Adults**: 3 g given intravenously every eight hours.
• **Infants and Children**: 150-250 mg/kg/day given intravenously in 3 or 4 divided doses.
• **Neonates**: The dosage should be 100 mg/kg/day given intravenously.
**Prophylaxis**: The usual dose is 1.5 g given intravenously with induction of anaesthesia for abdominal, pelvic and orthopaedic operations. This may be supplemented with two 750 mg intramuscular doses eight and sixteen hours later.
In cardiac, pulmonary, oesophageal and vascular operations, the usual dose is 1.5 g given intravenously with induction of anaesthesia, continuing with 750 mg given intramuscularly three times daily for a further 24 to 48 hours. In total joint replacement, 1.5 g cefuroxime powder may be mixed dry with each pack of methyl methacrylate cement polymer before adding the liquid monomer. As is the case with other antibiotics characterized by prevailing renal elimination, in order to prevent build-up effects in cases of renal
failure, we recommend that the dosage schemes listed below be followed in adult patients:

<table>
<thead>
<tr>
<th>Creatinine clearance (ml/min)</th>
<th>Max. Daily dose (mg/day)</th>
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<tbody>
<tr>
<td>10-20</td>
<td>1500</td>
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<tr>
<td>less than 10</td>
<td>750</td>
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</table>

Patients submitted to haemodialysis should be given a 750 mg additional dose of cefuroxime I.M. or I.V. after each dialysis. Cefuroxime may also be added to peritoneal dialysis solutions (usually 250 mg every two liters of dialysis fluid).

For patients submitted to continuous arteriovenous haemodialysis or high-flow blood filtration in intensive care units, the recommended dose is 750 mg twice daily.

For patients receiving low-flow blood filtration, follow the recommended dosage scheme for treatment in case of renal failure.

**Solution preparation Intramuscular:**
Add 3 ml water for injections to 750 mg Maxil. Shake gently to produce an opaque suspension.

**Intravenous:**

a. **Intravenous Bolus**
Dissolve Maxil in Water for Injections using at least 6 ml for 750 mg, or 15 ml for 1.5 g.

b. **Intravenous Infusion**
For short intravenous infusion (e.g. up to 30 minutes), 1.5 g may be dissolved in 50-100 ml Water for Injections. These solutions may be given directly into the vein or introduced into the tubing of the giving set if the patient is receiving parenteral fluids.

**CONTRA-INDICATIONS**
Hypersensitivity to cephalosporins antibiotics.

**PRECAUTIONS**
Cefuroxime is well tolerated, although a possible hypersensitivity cross-reaction with penicillins cannot be excluded, especially in the event of parenteral administration. Therefore, it should be given with caution to patients who have experienced anaphylactic reactions to penicillins.

The onset of any kind of allergic response requests the withdrawal of the drug and adoption of a suitable therapy, if necessary (e.g. adrenalin, antihistamines or corticosteroids). The concurrent or close administration of nephrotoxic drugs (kanamycin, streptomycin, colistin, vancomycin, polymyxin, neomycin, gentamicin) or potent diuretics (e.g. furosemide) is not recommended: the renal function of these patients should constantly be monitored, as well as that of elderly patients and patients with earlier impairment of renal function. Clinical experience has shown that it is unlikely for cefuroxime to cause problems of this kind if administered according to the recommended doses.

Like in other therapeutic schemes used in the treatment of meningitis, cases of mild or moderate hearing loss have been recorded with paediatric patients receiving cefuroxime sodium. In addition, persistence of H. influenzae positive cultures in the cerebrospinal fluid has been observed with cefuroxime sodium (and with other antibiotic treatments) after 18-36 hours; nevertheless, the clinical relevance of this finding is not known. Cases of pseudomembranous colitis have been recorded with virtually all types of broad spectrum antibiotics (including macrolides, semisynthetic penicillins and cephalosporins): consequently, it is critical to consider this diagnostic possibility in patients experiencing diarrhoea during a course of antibiotics.

This type of colitis can vary from mild to very severe forms. Treatment with broad spectrum antibiotics will alter the normal flora of colon and can facilitate clostridium growth. Studies have pointed out that a toxin produced by is the main cause of colitis associated with the use of antibiotics.

Milder forms of pseudomembranous colitis generally respond well to simple withdrawal of the drug. Other causes of colitis should be excluded.

**Pregnancy**
Although no experimental evidence exists of embryopathic or teratogenic effects ascribable to cefuroxime, like any other drug, should only be given to expecting mothers or infants when actually required and under close medical supervision.

**Lactation**
Cefuroxime is excreted in human milk; administer to nursing mothers with caution.
INTERACTIONS
Cefuroxime will not interfere with enzymatic tests for glycosuria. A slight interference can be observed if methods based on copper reduction (Benedict test, Fehling test, «Clinitest») are used. However, this is not likely to lead to false positives, as is the case with other cephalosporins. It is recommended that the glucose oxidase and hexokinase methods are used for the determination of glucose blood levels in patients receiving cefuroxime.

Cefuroxime will not interfere with the determination of creatinine in the alkaline picrate assay.

SPECIAL WARNING
The product will not affect driving or machine operating skills.

SIDE EFFECTS
Undesirable reactions to cefuroxime have only rarely been observed and are usually mild and transient in nature. Infrequent hypersensitivity reactions have been recorded including:
different types of skin rash (urticarial or maculopapular), urticaria, pruritis, interstitial nephritis, drug fever and very rarely anaphylaxis.

As with other cephalosporins, multiform erythema, Stevens-Johnson syndrome and toxic epidermal necrolysis (exanathematic necrolysis) have occasionally been observed. The prolonged use of the antibiotic can foster the development of non-susceptible microorganisms, e.g. Candida, which requests the adoption of appropriate measures or the withdrawal of the medication if required.

Gastrointestinal disorders (including very rarely symptoms of pseudomembranous colitis) can occur during or after treatment. The main alterations of blood parameters observed in a few patients have been decreased haemoglobin concentration, leucopenia, neutropenia and eosinophilia. During treatment with cephalosporins, (sometimes false) positive Coombs test results have been recorded, which is likely to interfere with blood compatibility tests.

Although transient increases of hepatic serum enzymes and Serum-bilirubin have occasionally been observed particularly in patients with underlying liver diseases, there is no evidence of hepatic harmfulness. Variations of renal function biochemical test results can be experienced: increased creatinine and/or azotemia and decreased creatinine clearance.

Renal function should be monitored as a precaution in case of impaired renal function.

Cases of haemolytic anaemia have been recorded after treatment with cephalosporins. IV administration can occasionally cause thrombophlebitis. If side effects set in, especially if they are not among those described in the data sheet, seek the advice of your family physician or pharmacist.

Incompatibility
It is advisable to avoid cefuroxime dilution in solutions containing sodium bicarbonate.

Cefuroxime should not be mixed in the same container with aminoglycosides.

Compatibility
1.5 g cefuroxime is compatible with 5 g azlocillin (in 50 ml solvent); the resulting solution is stable for 24 hours at 4°C or 6 hours at 25°C.

Cefuroxime (5 mg/ml) can be stored for 24 hours at 25°C in a 5% or 10% p/v injectable xylitol solution. Cefuroxime is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride. In addition, it is compatible with the most commonly used infusion fluids.

Cefuroxime is stable during 24 hours at 25°C in the following injectable solutions:
- Sodium chloride 0.9% p/v - Hartmann’s solution
- 5% Dextrose Injection - Ringer’s Injection
- 10% Dextrose Injection - 10% Invert Sugar in Water for Injection
- Lactated Ringer's Injection - M/6 Sodium Lactate Injection
- 0.18% w/v Sodium Chloride plus 4% Dextrose Injection
- 5% Dextrose and 0.9% Sodium Chloride Injection
- 5% Dextrose and 0.45% Sodium Chloride Injection
- 5% Dextrose and 0.225% Sodium Chloride Injection

Cefuroxime stability in a 0.9% p/v sodium chloride and 5% dextrose solution is not affected by the presence of hydrocortisone sodium phosphate.
Cefuroxime has also been found compatible for 24 hours at 25°C when mixed with: - Heparin (10 and 5 units/ml) in sodium chloride 0.9% injection.
- Potassium chloride (10 and 40 mEqL) in sodium chloride 0.9% injection.

OVERDOSAGE
Cephalosporins overdose can lead to cerebral irritation with resulting convulsions. Serum levels of cefuroxime are reduced by dialysis.

STORAGE CONDITIONS
Store between 15-25°C, away from light.
Color intensification of reconstituted solutions can be observed during storage; the solutions are stable for 5 hours if stored at temperatures lower than 25°C and for 48 hours if stored at 4°C.
1.5 g Maxil constituted with 15 ml Water for Injections may be added to metronidazole injection (500 mg/100 ml) and both retain their activity for up to 24 hours below 25°C.

PRESENTATIONS

Vials
MAXIL 750 IM/IV:
Sterile Cefuroxime (as sodium) 750 mg
MAXIL 1500 IV:
Sterile Cefuroxime (as sodium) 1500 mg