

MAXIL®

(Cefuroxime sodium)

ACTION

Maxil is a cephalosporin antibiotic which is resistant to most β -lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. MAXIL has been shown to be active against most strains of the following organisms:

Gram-negative aerobes: Haemophilus influenzae (including ampicillin-resistant strains) Haemophilus parainfluenzae, Branhamella catarrhalis, Neisseria gonorrhoea, Neisseria meningitidis, Escherichia coli, Klebsiella sp., Enterobacter sp., Citrobacter sp., Salmonella sp., Shigella sp., Proteus mirabilis, Providencia rettgeri, Morganella morganii. **Gram-positive aerobes:** Staphylococcus aureus (including strains which are resistant to penicillin but not the rare methicillin strains) Staphylococcus epidermidis, Streptococcus pyogenes (and other Streptococci) and Streptococcus pneumoniae. **Anaerobes:** Peptococcus and Peptostreptococcus sp., Clostridium sp., Bacteroides sp., Fusobacterium sp.

INDICATIONS

Maxil is indicated in the treatment of the following diseases:

1. Respiratory tract infections including pneumoniae
2. Urinary tract infections
3. Skin and skin structure infections
4. Septicemia
5. Meningitis
6. Gonorrhoea
7. Bone and joint infections
8. Mixed infections in which several organisms have been isolated
9. In certain cases of confirmed or suspected gram-negative sepsis, or in patients with other serious infections in which the causative organism has not been identified
10. Preoperative prophylaxis

DOSAGE AND ADMINISTRATION

Maxil administered by deep intramuscular injection, by slow intravenous injection over 3-5 minutes, or by intravenous infusion.

Adults: Usual dose is 750mg every 8 hours. The frequency of IM or IV injections can be increased to 6 hourly if necessary, giving total doses of 3-6 g daily.

Infants and children: 30-60mg/kg body weight daily, increased to 100mg/kg daily if necessary, given in 3 or 4 divided doses.

Neonates: may be given similar total daily doses of that given to children but administered in 2 or 3 divided doses.

Other Recommendations:

Meningitis:

Adults: 3g every 8 hours.

Infants and children: 200-240 mg/kg daily in 3 or 4 divided doses, decreased to 100mg/kg daily after 3 days.

Neonates: 100 mg/kg daily, decreased to 50 mg/kg daily.

Data are not yet sufficient to recommend a dose for intrathecal administration.

Gonorrhoea: 1.5 g by intramuscular injection.

Surgical prophylaxis: 1.5 g intravenously prior to the procedure followed by 750mg intravenously or intramuscularly every 8 hours for up to 24 to 48 hours.

In total joint replacement: 1.5 g of Maxil powder may be mixed with the methylmethacrylate cement monomer before adding the liquid polymer.

Dosage in impaired renal function: The dosage adjustment in renal insufficiency is only necessary if the creatinine clearance is less than 20ml/minute. If creatinine clearance is 10-20 ml/minute: 750 mg twice daily. If creatinine clearance is less than 10ml/minute: 750 mg once daily.

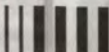
Patients undergoing haemodialysis should receive a further 750 mg at the end of each dialysis session, and those on continuous ambulatory peritoneal dialysis 750mg twice daily.

Preparation of dosage form and stability:

Intramuscular reconstitution: Add 3ml of sterile water for injection to each 750 mg vial.

Shake gently to produce an opaque suspension. Inject into a large muscle mass.

Intravenous reconstitution: Reconstitute with sterile water for injection as follows:




Vial size

750 mg
1.5 g

Sterile water for injection added

6 ml
15 ml

For short intravenous infusion (e.g. up to 30 minutes) 1.5g may be dissolved in 50 ml water for injection. 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. Maxil is compatible with the more commonly used intravenous fluids e.g.:

5 % Dextrose.

0.9% Sodium chloride.

After reconstitution for intramuscular and for intravenous use, suspensions and solutions retain their potency for 24 hours at room temperature or for 48 hours if refrigerated at 5°C.

More dilute solutions maintain satisfactory potency for 24 hours at room temperature and for 72 hours if refrigerated at 5°C.

Use of sodium bicarbonate is not recommended for dilution. Solutions may vary in color from light yellow to amber, depending on concentration and diluent. Cefuroxime powder, suspensions and solutions tend to darken, this does not affect their potency. The admixture of Beta-lactam antibacterials and aminoglycosides may result in substantial mutual inactivation. They should be administered at separate sites.

CONTRAINDICATIONS

Cefuroxime is contraindicated in patients with known allergy to cephalosporin antibiotics.

WARNINGS

- Careful inquiry should be made for previous hypersensitivity reactions to cephalosporins and penicillins.
- Adjustment of dose should be considered in patients with severe renal impairment.

PRECAUTIONS

- Prolonged use of anti-infectives may result in overgrowth of non-susceptible organisms.
- Cefuroxime may cause a false negative reaction in the Ferricyanide test for blood glucose.
- A false positive direct Coombs test has occurred in some patients receiving cephalosporins.

SIDE EFFECTS

Side effects are of mild and transient nature. These include: GI disturbances (nausea, vomiting, abdominal pain), hypersensitivity such as urticaria, pruritus and drug fever.

OVERDOSAGE

Serious acute hypersensitivity reactions may require adrenaline and other emergency measures.

PRESENTATION**Vials**

MAXIL 750 IM/IV: Sterile Cefuroxime (as sodium) USP 750 mg
MAXIL1500 IV: Sterile Cefuroxime (as sodium) USP 1500 mg

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.



Keep medicament out of the reach of children.
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