For The Use Of A Registered Medical Practitioner Or A Hospital Use Only

AMERICAN Fazolin 1g Cefazolin for Injection USP

Composition :
Each vial contains :
Cefazolin Sodium (Sterile) USP
eq. to Cefazolin 1000mg

ACTION AND CLINICAL PHARMACOLOGY

Cefazolin sodium is a cephalosporin antibiotic for parenteral administration. It exerts its bacterial effect by inhibiting bacterial cell wall synthesis.

INDICATIONS AND CLINICAL USES

Cefazolin for Injection, USP may be indicated in the treatment of the following infections when caused by susceptible strains of the listed organisms:

·Respiratory Tract Infections caused by Streptococcus pneumoniae, Klebsiella pneumoniae, Hemophilus influenzae, Staphylococcus aureus (penicillin-sensitive and penicillin-resistant) and group A beta-hemolytic streptococci.

·Urinary Tract Infections caused by Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae and some strains of enterobacter and enterococci.

·Skin And Soft Tissue Infections caused by Staphylococcus aureus (penicillin- sensitive and penicillin-resistant), group A beta-hemolytic streptococci and other strains of streptococci.

·Bone And Joint Infections caused by Staphylococcus aureus.

·Septicemia caused by Streptococcus pneumoniae, Staphylococcus aureus (penicillin-sensitive and penicillin-resistant), Proteus mirabilis, Escherichia coli and Klebsiella pneumoniae.

·Endocarditis caused by Staphylococcus aureus (penicillin-sensitive and penicillin-resistant) and group A beta-hemolytic streptococci.

In order to determine the susceptibility of the causative organism to cefazolin sodium, appropriate culture and susceptibility studies should be performed. (See MICROBIOLOGY for disc susceptibility tests and dilution techniques.)

Most strains of Enterococci, indole positive Proteus (P. vulgaris), Enterobacter cloacae, Morganella morganii, Providencia rettgeri and methicillin-resistant staphylococci are resistant. Serratia, Pseudomonas, and Acinetobacter calcoaceticus (formerly Mima and Herellea species) are almost uniformly resistant to cefazolin. (See MICROBIOLOGY.)

Perioperative Prophylaxis

In patients undergoing potentially contaminated surgical procedures, and in patients in whom infection would pose a serious risk (e.g., during open-heart surgery and prosthetic arthroplasty), the preoperative, intraoperative, and postoperative administration of Cefazolin for Injection, USP may reduce the incidence of certain postoperative infections.

Identification of the causative organisms should be made by culture should signs of infection occur, so that appropriate therapy may be instituted.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefazolin for Injection, USP and other antibacterial drugs, Cefazolin for Injection, USP should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS

Cefazolin for Injection, USP is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS

Cefazolin for Injection, USP should be used with caution in penicillin-allergic patients. There is clinical evidence of partial cross-allergenicity of the penicillins and the cephalosporins. There are instances of patients who have had reactions to both penicillins and cephalosporins (including fatal anaphylaxis after parenteral use). Clinical and laboratory evidence of partial cross- allergenicity for these two drug classes exists.

Cefazolin for Injection, USP should be administered cautiously and then only when absolutely necessary to any patient who has demonstrated allergy, particularly to drugs. Immediate emergency treatment with epinephrine is indicated for serious anaphylactoid reactions. As indicated oxygen, intravenous steroids, and airway management including intubation, should also be employed.

There have been reports of pseudomembranous colitis with the use of cephalosporins. It is therefore important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing Cefazolin for Injection, USP in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug- resistant bacteria.

PRECAUTIONS

The overgrowth of non-susceptible organisms may result from the prolonged use of Cefazolin for Injection, USP. It is essential that the patient be carefully observed.

In patients with a history of lower gastrointestinal disease, and in particular, colitis, Cefazolin for Injection, USP should be prescribed with caution.

Positive direct and indirect ' tests have been reported during treatment with cefazolin. These may also occur in neonates whose mothers received cephalosporins before delivery. The clinical significance of this effect has not been established.

Use in Renal Impairment

Drug Interactions

The renal tubular secretions of cefazolin may be decreased when probenecid is used concurrently, resulting in increased and prolonged cefazolin blood levels.

ADVERSE REACTIONS

The following reactions have been reported.

Allergic

Allergic reactions occur infrequently and include: Anaphylaxis, eosinophilia, itching, drug fever, and skin rash.

Gastrointestinal

Diarrhea, oral candidiasis (oral thrush), vomiting, nausea, stomach cramps, anorexia. During antibiotic treatment, symptoms of pseudomembranous colitis can appear. There have been rare reports of nausea and vomiting.

Hematologic

Neutropenia, anemia, leukopenia, thrombocythemia, positive direct and indirect antiglobulin (Coombs') tests.

Hepatic and Renal

Transient increases in AST (SGOT), ALT (SGPT), BUN and alkaline phosphatase levels have been observed without clinical evidence of hepatic or renal impairment. Transient hepatitis and cholestatic jaundice have been reported rarely, as with some penicillins and some other cephalosporins.

Local Reactions

Phlebitis at the site of injection has occurred rarely. Infrequently there is pain at the site of injection following intramuscular injection. Some induration has been reported.

DOSAGE AND ADMINISTRATION

After reconstitution Cefazolin for Injection, USP may be administered either intramuscularly or intravenously. In both cases, total daily dosages are the same.

Treatment should be continued in beta-hemolytic streptococcal infections for at least 10 days to

minimize possible complications associated with the disease.

Cefazolin sodium has been administered in dosages of 6 grams per day in serious infections such as endocarditis.

Perioperative Prophylactic Use:

The recommended dosage regimen to prevent postoperative infection in contaminated or potentially contaminated surgery is:

a) One gram intravenous or intramuscular administered ½ hour to 1 hour prior to the start of surgery so that at the time of the initial surgical incision, adequate antibiotic levels are present in the serum and tissues.

b) For lengthy operative procedures (e.g., 2 hours or more) 0.5-1 g administered intravenously or intramuscularly during surgery. (Administration should be modified according to the duration of the operative procedure and the time of greatest exposure to infective organisms.)

c) 0.5 gram to 1 gram intravenous or intramuscular every 6 to 8 hours for 24 hours postoperatively. The prophylactic administration of cefazolin sodium maybe continued for 3 to 5 days following the completion of surgery in which the occurrence of infection may be particularly devastating (e.g., open-heart surgery and prosthetic arthroplasty).

Pediatric Dosage

A total daily dosage of 25 to 50 mg per kg (approximately 10 to 20 mg per pound) of body weight, divided into three or four equal doses, is effective for most mild to moderately severe infections in children. Duration of therapy in most cases should be 5 to 10 days.

Treatment should be continued in beta-hemolytic streptococcal infections for at least 10 days to minimize possible complications associated with the disease.

For severe infections, the total daily dosage may be increased to 100 mg per kg (45 mg per pound) of body weight. The use of cefazolin in prematures and in infants under one month is not recommended since the safety for use in these patients has not been established.

Treatment with 60 percent of the normal daily dose may be administered in divided doses every 12 hours to children with mild to moderate renal impairment (CCr 0.67 – 1.17 mL/s). Children with moderate to severe renal impairment (CCr 0.33 – 0.87 mL/s) should be given 25 percent of the normal daily dose in equally divided doses every 12 hours, and children with severe renal impairment (CCr 0.08 – 0.33 mL/s) should receive 10 percent of the normal daily dose every 24 hours.

Administration:

NOTE: See RECONSTITUTION section for reconstitution and dilution directions.

For Intramuscular Use:

Inject the reconstituted solution into a large muscle mass. Pain on injection of Cefazolin sodium occurs infrequently.

For Intravenous Use:

The intravenous route is preferred for patients with septicemia, peritonitis, or other severe life- threatening infections.

Direct Intravenous (bolus) Injection:

Inject the appropriately diluted reconstituted solution slowly over 3 to 5 minutes directly into vein or through tubing for patients receiving parenteral fluids. (See list of solutions for intravenous infusion in RECONSTITUTION.)

Intermittent or Continuous Intravenous Infusion:

The reconstituted solution can be administered along with primary intravenous fluid management programs in a volume control set or in a separate secondary intravenous bottle. (See list of solutions for intravenous infusion in RECONSTITUTION.) It is desirable to discontinue the administration of other solutions during the infusion of cefazolin.

Cefazolin for Injection, USP, Pharmacy Bulk Packages are for intravenous use only following reconstitution and transfer into syringes.

After transfer of the contents from the Pharmacy Bulk Packages into syringes, cefazolin can be administered in intermittent or continuous infusion via a syringe pump.

RECONSTITUTION

When reconstituted, the vial should be SHAKEN WELL and inspected visually for particulate matter prior to administration. The drug solution should be discarded if particulate matter is evident in reconstituted fluids.

Reconstituted Cefazolin for Injection, USP is stable for 24 hours at controlled room temperature not exceeding 25 °C, or for 72 hours under refrigeration (2 °C to 8 °C) protected from light, from the time of initial puncture of the stopper.

Single-dose Vials: Reconstitute according to the Single-dose Vial Reconstitution. SHAKE TO DISSOLVE ALL POWDER. For further dilution of the reconstituted solution, a minimum of 10 mL of Sterile Water for Injection should be used.

Pharmacy Bulk Vial: Add, according to the Pharmacy Bulk Vial Dilution, 45 mL or 96 mL Sterile Water for Injection, or Sodium Chloride Injection 0.9%. One of the solutions listed below under For Intermittent or Continuous Intravenous Infusion may be used to further dilute aliquots. SHAKE TO DISSOLVE ALL POWDER. The Pharmacy Bulk Vial is intended for multiple dispensing and intravenous use only employing a single puncture. Any unused stock solution remaining after a period of 8 hours should be discarded. The use of pharmacy bulk vials is restricted to hospitals with a recognized intravenous admixture program.

Extended use of Intravenous Admixtures

Although intravenous admixtures may often be physically and chemically stable for longer periods, due to microbiological considerations, they are usually recommended for use within 24 hours at room temperature or 72 hours when refrigerated (2 °C to 8 °C), from the time of initial puncture of the stopper.

Storage : Store protected from light at a temperature not exceeding 30°C.

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