AMPCILLIN AND SULBACTAM FOR INJECTION, USP

WARNINGS

Hypersensitivity

Serious or occasionally fatal hypersensitivity (anaphylactic) reactions as well as other serious allergic reactions have been reported in association with Ampicillin and sulbactam for injection. In addition, cross-sensitivity with other beta-lactam antibacterials has been documented in up to 30% of penicillin-allergic patients. Therefore, Ampicillin and sulbactam for injection should not be administered to patients with a history of allergic reactions to penicillin, beta-lactam antibacterials, or other drugs. More information is contained in the INDICATIONS AND USAGE section.

CONTRAINDICATIONS

Ampicillin and sulbactam for injection is contraindicated in patients with a history of hypersensitivity to Ampicillin, sulbactam, or any component of the formulation. Ampicillin and sulbactam for injection is also contraindicated for use in patients with: a history of ampicillin-associated exfoliative dermatitis; a history of oropharyngeal candidiasis caused by Candida albicans; a history of severe reactions to beta-lactam antibacterials; or sulbactam-associated adverse drug reactions, particularly those reported to be severe or severe enough to cause hospitalization. See WARNINGS section for information on severe skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis in patients with a history of penicillin- or ampicillin-associated exfoliative dermatitis.

ADVERSE REACTIONS

The safety and efficacy of Ampicillin and sulbactam for injection have been established in pediatric patients for the treatment of serious infections due to susceptible bacteria, and in adults for the treatment of serious infections due to susceptible bacteria except those included in the contraindications section. See WARNINGS section for information on severe skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis in patients with a history of penicillin- or ampicillin-associated exfoliative dermatitis.

PRECAUTIONS-Pediatric Use

While Ampicillin and sulbactam for injection is usually well tolerated, the following adverse reactions have been reported in pediatric patients:

Diarrhea: Mild diarrhea occurred in 13% to 20% of pediatric patients treated with Ampicillin and sulbactam for injection. Diarrhea is more likely to occur in infants and young children and is associated with the dose and duration of drug therapy. The relationship of diarrhea to the drug therapy is not known.

Gastrointestinal Disorders: Diarrhea has been related to Ampicillin and sulbactam for injection.

Hepatic: Increased ALT, AST, total bilirubin, and alkaline phosphatase were related to Ampicillin and sulbactam for injection.

Miscellaneous: Anaphylaxis and exfoliative dermatitis (including toxic epidermal necrolysis), Stevens-Johnson syndrome, and erythema multiforme have been reported.

Nursing Mothers

Low concentrations of Ampicillin and sulbactam are excreted in human milk. Ampicillin and sulbactam for injection should not be administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Ampicillin and sulbactam for injection have been established in pediatric patients one year of age and older for the treatment of infections due to susceptible bacteria. See WARNINGS section for information on severe skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis in patients with a history of penicillin- or ampicillin-associated exfoliative dermatitis.

ADVERSE REACTIONS

Adult Patients

Ampicillin and sulbactam for injection is generally well tolerated. The following adverse reactions have been reported in clinical trials.

Local Adverse Reactions

Dyspnea.

Peptide Adverse Reactions

Hypersensitivity

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Skin and Subcutaneous Tissue Disorders: Toxic epidermal necrolysis, Stevens-Johnson syndrome, exfoliative dermatitis, acute generalized exanthematous pustulosis (AGEP), erythema multiforme, toxic epidermal necrolysis and urticaria (see WARNINGS).

Patients with Renal Impairment

The following recommendations: in such patients should be administered less frequently in renal function. The dose of ampicillin and sulbactam for injection with the ratio of one to the other will remain constant whatever the degree of protein binding and pharmacokinetics profile of sulbactam according to susceptibility testing of the original pathogen, if any, of the compatible diluents described in this insert. Solutions for injection should not exceed 4 grams per day. When concomitant therapy with aminoglycosides is indicated, the total dose of sulbactam corresponding plasma levels attained during the relative short administration of the stated volumes.

DOSAGE AND ADMINISTRATION

Ampicillin and sulbactam for injection may be administered by each dose of intravenous injection over of at least 30 minutes.

For IV administration, the dose may be given by slow intravenous injection over at least 1 hr or 15 hrs or can also be delivered in greater doses to 10% to 15% of a 1000 mL of a compatible diluent for injection, such as 5% Dextrose Injection or 0.9% Sodium Chloride Injection.

In patients with impaired renal function, the total amount of ampicillin and sulbactam for injection, USP sterile powder for injection should be divided into 2 to 4 equal doses per day.

Pediatric Patients 1 Year of Age or Older:

The recommended daily dose of ampicillin and sulbactam for injection in pediatric patients is 100 mg per kg per day, administered intravenously in equally divided doses every 6 hours.

The recommended dose of ampicillin and sulbactam for injection in pediatric patients is 20 mg/kg/day divided into 2 to 4 equal doses per day. The total dose of sulbactam should not exceed 4 grams per day.

Impaired Renal Function

In patients with impaired renal function the elimination kinetics of ampicillin and sulbactam are substantially increased. The safety and efficacy of ampicillin and sulbactam for injection administered intravenously in constant infusion, USP sterile powder for injection should be 5% Dextrose Injection or 0.9% Sodium Chloride Injection.

TABLE 5:

Ampicillin And Sulbactam For Injection Dose

<table>
<thead>
<tr>
<th>Volume of Administration</th>
<th>Withdrawal Volume</th>
<th>Ampicillin Ampicillin</th>
<th>Sulbactam Sulbactam</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.5 g</td>
<td>3.2 mL</td>
<td>1 g/mL g/mL</td>
<td>2.5 g/mL g/mL</td>
</tr>
<tr>
<td>22 mg</td>
<td>4 mL</td>
<td>1.5 g/mL g/mL</td>
<td>3 g/mL g/mL</td>
</tr>
</tbody>
</table>

There is sufficient excess powder to allow withdrawal and administration of the stated doses.

Animal Pharmacology

While reversible glycosylation was observed in laboratory animals, this phenomenon was slow and is not expected to develop at the therapeutic doses and corresponding plasma levels attained during the relative short periods of combined ampicillin/sulbactam therapy in man.

HOW SUPPLIED

Ampicillin and Sulbactam for Injection, USP is supplied as a sterile,loffy dry powder in glass vials. The following packages are available:

Vial containing 1.5 g (NDC 44627-210-10) equivalent of Ampicillin and Sulbactam for Injection, USP (2 g ampicillin as the sodium salt plus 0.5 g sulbactam as the sodium salt) and sulbactam for injection per mL (10 mg ampicillin/25 mg sulbactam per mL). An appropriate volume should not be diluted further with more than 25 mL of sterile water for injection or 100 mL of a compatible diluent (see DIRECTIONS FOR USE - Preparation for Intravenous Injection section).

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OTHER SIZE PACKAGE AVAILABLE

Pharmacy Bulk Package containing 15 g (NDC 44627-215-01) equivalent of Ampicillin and Sulbactam for Injection, USP (750 mg ampicillin as the sodium salt plus 150 mg sulbactam as the sodium salt).

DISTRIBUTED BY

WG Critical Care, LLC

Revised November 2018