Ampicillin and Sulbactam for Injection, USP

For the treatment of infections caused by susceptible bacteria (see Indications).

Ampicillin and Sulbactam for Injection, USP is a semisynthetic antibacterial combination consisting of the semisynthetic antibacterial ampicillin sodium and the beta-lactamase inhibitor sulbactam sodium for intravenous and intramuscular administration.

Ampicillin, when used alone, is bactericidal against many susceptible bacteria by inhibiting cell wall synthesis. Ampicillin and Sulbactam for Injection contains sulbactam, an inhibitor of beta-lactamases. The sulbactam component of the combination is bacteriostatic by itself but enhances the antimicrobial activity of ampicillin against many beta-lactamase-producing bacteria.

Ampicillin has been found to be approximately 28% reversibly bound to human serum protein. The mean serum half-life of both drugs is approximately 1 hour in healthy volunteers.

The mean amount of ampicillin and sulbactam excreted unchanged in the urine is approximately 75% and 85%, respectively. The mean amount of both the ampicillin and sulbactam are excreted in the feces as well as in the urine.

The mean serum half-life of both ampicillin and sulbactam is approximately 1 hour in healthy volunteers.

The following average levels of ampicillin and sulbactam were measured in the tissues and fluids of healthy adult volunteers:

<table>
<thead>
<tr>
<th>Tissue/Fluid</th>
<th>Average Concentration (mcg/mL or mcg/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood</td>
<td>17-19</td>
</tr>
<tr>
<td>Tissue</td>
<td>12-18</td>
</tr>
<tr>
<td>Urine</td>
<td>12-16</td>
</tr>
<tr>
<td>Saliva</td>
<td>2-5</td>
</tr>
</tbody>
</table>

The pharmacokinetics of ampicillin and sulbactam are similar in adults and children. After a single intravenous dose, the peak serum concentrations of ampicillin and sulbactam are similar in adults and children.

Ampicillin and sulbactam are removed by hemodialysis. In patients with end-stage renal disease, the mean plasma concentrations of ampicillin and sulbactam were reduced by approximately 50% after 4 hours of hemodialysis.

DOSAGE AND ADMINISTRATION

Ampicillin and Sulbactam for Injection should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. Ampicillin and Sulbactam for Injection is not recommended for use in the treatment of viral infections.

The dose of Ampicillin and Sulbactam for Injection in each patient should be determined by the severity of the infection and susceptibility of the pathogen. Ampicillin and Sulbactam for Injection should be administered at intervals that will maintain high serum concentrations of both drugs in the presence of sulbactam at a constant 2 parts ampicillin to 1 part sulbactam.

The concentration of ampicillin and sulbactam in various body fluids is shown in the table below.

**CONTRAINDICATIONS**

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**PRECAUTIONS**

Pediatric Use

The safety and effectiveness of Ampicillin and Sulbactam for Injection in pediatric patients weighing less than 40 kg has not been established.

**SIDE EFFECTS**

**Preclinically Observed Effects on Clinical Laboratory Tests**

There have been reports of a transient increase in liver enzyme levels, including SGOT, SGPT, alkaline phosphatase, and bilirubin. These effects were usually reversible, and there were no significant symptoms or clinical consequences associated with these changes. In a single case of a 3-month-old premature infant, SGOT levels increased from 64 units/L (normal, 0-40 units/L) to 248 units/L after 72 hours of treatment with Ampicillin and Sulbactam for Injection. The infant was temporarily withdrawn from the drug on the fifth day and then readministered with no further clinical problem.

**CLINICAL STUDIES**

In a clinical study in 34 patients, mean peak serum concentrations of ampicillin and sulbactam were 36 mcg/mL and 14 mcg/mL, respectively, 1 hour after a 3-g dose of Ampicillin and Sulbactam for Injection. The mean trough serum concentrations of ampicillin and sulbactam were 18 mcg/mL and 5 mcg/mL, respectively, 6 hours after a 3-g dose of Ampicillin and Sulbactam for Injection.

**EDUCATION**

This section provides general information about Ampicillin and Sulbactam for Injection and other antibacterial drugs. Ampicillin and Sulbactam for Injection is an injectable antibacterial combination consisting of ampicillin sodium and sulbactam sodium. Ampicillin is a broad-spectrum penicillin, and sulbactam is an inhibitor of beta-lactamase. The antibacterial activity of ampicillin is enhanced by sulbactam.

**INDICATIONS**

Ampicillin and Sulbactam for Injection is indicated for the treatment of infections caused by susceptible bacteria (see Indications).

**CONTRAINDICATIONS**

**PRECAUTIONS**

Pediatric Use

**SIDE EFFECTS**

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