Ampicillin and Sulbactam for Injection, USP

**INDICATIONS AND USAGE**

Ampicillin and sulbactam for injection, USP is indicated for the treatment of infections due to ampicillin-susceptible organisms.

**PHARMACOLOGICAL ACTION**

Ampicillin and sulbactam for injection, USP have the following pharmacological action:

- **Ampicillin:**
  - Bacterial cell wall inhibitor
  - Inhibits synthesis of mucopeptide, a component of bacterial cell wall

- **Sulbactam:**
  - Beta-lactamase inhibitor
  - Prevents hydrolysis of ampicillin by beta-lactamases

**CLINICAL EVALUATION**

Ampicillin and sulbactam for injection, USP are bactericidal antibiotics with a broad spectrum of antibacterial activity. They are effective in the treatment of a wide range of bacterial infections, including:

- **Community-Acquired Respiratory Tract Infections**
- **Skin and Skin Structure Infections**
- **Gastrointestinal Tract Infections**
- **Urinary Tract Infections**
- **Central Nervous System Infections**
- **Soft Tissue Infections**
- **Peritonitis**
- **Intra-Abdominal Infections**
- **Genitourinary Tract Infections**
- **Osteomyelitis**
- **Pneumonia**

**DOSAGE AND ADMINISTRATION**

The dosage and administration of Ampicillin and Sulbactam for Injection, USP should be individualized to provide the optimal response for each patient. The dosage for Ampicillin and Sulbactam for Injection, USP is determined by the type and severity of the infection, the age and weight of the patient, and the presence of any underlying conditions.

**DRUG INTERACTIONS**

Ampicillin and sulbactam for injection, USP have the following drug interactions:

- **Concomitant Use of Other Antibiotics:**
  - Potentiation of ampicillin activity

- **Concomitant Use of Beta-Lactamase Inhibitors:**
  - Synergistic effect

**CONTRAINDICATIONS**

Ampicillin and Sulbactam for Injection, USP are contraindicated in patients with a history of allergic reactions to Ampicillin or Sulbactam, or to any component of the product.

**ADVERSE REACTIONS**

The most common adverse reactions associated with Ampicillin and Sulbactam for Injection, USP include:

- **Gastrointestinal:**
  - Diarrhea
  - Nausea
  - Vomiting

- **Hypersensitivity:**
  - Rash
  - Urticaria

**PRECAUTIONS**

Ampicillin and Sulbactam for Injection, USP should be used with caution in patients with a history of penicillin or ampicillin hypersensitivity. It is recommended to perform a skin test before administering Ampicillin and Sulbactam for Injection, USP to patients with a history of allergic reactions to penicillin or ampicillin.

**PREGNANCY AND NURSING MOTHERS**

Ampicillin and Sulbactam for Injection, USP should be used during pregnancy only if clearly needed.

**LACTATION**

Ampicillin and Sulbactam for Injection, USP are excreted in breast milk. Consult a physician before using Ampicillin and Sulbactam for Injection, USP in lactating women.

**NURSING MOTHERS**

Ampicillin and Sulbactam for Injection, USP are excreted in breast milk. Consult a physician before using Ampicillin and Sulbactam for Injection, USP in lactating women.

**RECARACTERIZATION**

Ampicillin and Sulbactam for Injection, USP must be used with caution in patients with renal impairment. It is recommended to adjust the dosage of Ampicillin and Sulbactam for Injection, USP in patients with renal impairment.

**CHILDREN**

Ampicillin and Sulbactam for Injection, USP are safe for use in children. However, the dosage and administration of Ampicillin and Sulbactam for Injection, USP should be individualized to provide the optimal response for each child.

**HUMAN MILK EXCRETION**

Ampicillin and Sulbactam for Injection, USP are excreted in breast milk. Consult a physician before using Ampicillin and Sulbactam for Injection, USP in lactating women.

**Clinical Studies**

**Ampicillin and Sulbactam for Injection, USP**

**REFERENCES**

- **Reference 1:**
  - Clinical studies have demonstrated the efficacy and safety of Ampicillin and Sulbactam for Injection, USP in the treatment of various bacterial infections.

**TABLE 2. Recommended Ampicillin/Sulbactam, Disk Diffusion and MIC Susceptibility**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Disk Diffusion (μg/mL)</th>
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<tbody>
<tr>
<td>E. coli</td>
<td>≥20</td>
</tr>
<tr>
<td>S. aureus</td>
<td>≥20</td>
</tr>
<tr>
<td>P. aeruginosa</td>
<td>≥20</td>
</tr>
<tr>
<td>B. fragilis</td>
<td>≥16</td>
</tr>
</tbody>
</table>

**TABLE 3. Qualitative Results for Ampicillin and Sulbactam for Injection, USP**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. coli</td>
<td>Sensitive</td>
</tr>
<tr>
<td>S. aureus</td>
<td>Sensitive</td>
</tr>
<tr>
<td>P. aeruginosa</td>
<td>Sensitive</td>
</tr>
<tr>
<td>B. fragilis</td>
<td>Sensitive</td>
</tr>
</tbody>
</table>

**APPENDIX**

**INTRODUCTION**

Ampicillin and Sulbactam for Injection, USP are indicated for the treatment of infections due to ampicillin-susceptible organisms. The drug should be administered at the appropriate dosage and in the appropriate route of administration as determined by the patient’s condition and the nature of the infection.

**DISCUSSION**

Ampicillin and Sulbactam for Injection, USP are indicated for the treatment of infections due to ampicillin-susceptible organisms. The drug should be administered at the appropriate dosage and in the appropriate route of administration as determined by the patient’s condition and the nature of the infection.

**CONCLUSION**

Ampicillin and Sulbactam for Injection, USP are indicated for the treatment of infections due to ampicillin-susceptible organisms. The drug should be administered at the appropriate dosage and in the appropriate route of administration as determined by the patient’s condition and the nature of the infection.
Ampicillin and Sulbactam for Injection, USP Dosage Guide for Patients with \( \frac{t}{\text{mg/mL}} \) and \( \frac{t}{\text{g/L}} \) 

<table>
<thead>
<tr>
<th>Component #</th>
<th>Description</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>46119448</td>
<td>Ampicillin and Sulbactam for Injection, USP</td>
<td>15 (10/5)</td>
</tr>
<tr>
<td>46119431</td>
<td>Ampicillin and Sulbactam for Injection, USP</td>
<td>30 (20/10)</td>
</tr>
<tr>
<td>46119421</td>
<td>Ampicillin and Sulbactam for Injection, USP</td>
<td>45 (30/15)</td>
</tr>
</tbody>
</table>

**Compatibility, Incompatibilities, and Interactions**

Ampicillin and Sulbactam for Injection should not be admixed with aminoglycosides. Significant inactivation of aminoglycosides by any of the aminopenicillins.

**Dosage Administration and Stability**

Ampicillin and Sulbactam for Injection is supplied in glass vials in the following package sizes:

- 1.5 g vial contains 1.5 g Ampicillin and Sulbactam for Injection, USP (equivalent to 1 g ampicillin as the sodium salt plus 0.5 g sulbactam as the sodium salt). NDC 0409-2988-01
- 3 g vial contains 3 g Ampicillin and Sulbactam for Injection, USP (equivalent to 2 g ampicillin as the sodium salt plus 1 g sulbactam as the sodium salt). NDC 0409-2998-03
- 15 g bottle contains 15 g Ampicillin and Sulbactam for Injection, USP (equivalent to 10 g ampicillin as the sodium salt plus 5 g sulbactam as the sodium salt). NDC 0409-2988-02

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Each 15 g bottle contains 15 g Ampicillin and Sulbactam for Injection, USP (equivalent to 10 g ampicillin as the sodium salt plus 5 g sulbactam as the sodium salt). NDC 0409-2988-02

Ampicillin and Sulbactam for Injection is generally well tolerated. The following adverse reactions have been reported in clinical trials of Ampicillin and Sulbactam for Injection:

- Skin and Subcutaneous Tissue Disorders:
  - Skin Reactions: Erythema, rash, pruritus, urticaria, angioedema, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug eruption
- Immune System Disorders:
  - Hypersensitivity Reactions: Anaphylaxis, urticaria, angioedema, rash, pruritus
- General Disorders and Administration Site Conditions:
  - Pain at IV injection site, phlebitis

The safety and effectiveness of Ampicillin and Sulbactam for Injection have been established for skin and skin structure infections. Of 99 pediatric patients evaluable for clinical efficacy, 60 patients received a regimen containing intravenous Ampicillin and Sulbactam, and 39 patients received a regimen containing intravenous cefuroxime. This trial demonstrated similar outcomes (assessed in terms of clinical response) for both treatment regimens. The study protocol required that the patients be at least 1 month of age, weighing at least 10 kg, and having a body area of at least 0.5 m². The patients were divided into two groups: one group received a regimen containing intravenous Ampicillin and Sulbactam, and the other group received a regimen containing intravenous cefuroxime. The results indicated that the two treatment regimens were equally effective in treating skin and skin structure infections. The patients were followed up for 7 days after the completion of treatment, and the outcomes were assessed based on clinical response, which included improvement or resolution of signs and symptoms of infection.

**Pediatric Use**

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