Piperacillin and Tazobactam for Injection and aminoglycosides should not be co-administered. Piperacillin significantly reduce tobramycin concentrations in hemodialysis patients.

Bacteremia

Patients with bacteremia due to 
Staphylococcus aureus

Pseudomonas aeruginosa

Fungal infections

Clinical studies have shown that Piperacillin and Tazobactam are generally well tolerated. The common adverse reactions reported in clinical trials are:

- Diarrhea (20%)
- Nausea (5.8%)
- Dyspepsia (1.9%)

Intravenous Infusion

Intravenous infusion of this drug should not be given at the same time as aminoglycosides. Piperacillin may inactivate aminoglycosides by converting them to inactive compounds. Aminoglycosides are recommended for separate administration.

12.3 Pharmacokinetics

Single dose vials should be used immediately after reconstitution. Stability of piperacillin and tazobactam for injection is 24 hours at room temperature and 7 days refrigerated. The following adverse reaction has also been reported for piperacillin and tazobactam:

- Hypersensitivity reactions, anaphylaxis, and anaphylactoid reactions (including shock) have been reported in patients treated with piperacillin and tazobactam. These reactions are characterized by manifestations such as cardiovascular collapse, facial edema, stridor, bronchospasm, and angioedema. Other symptoms may include urticaria, rash, pruritus, and fever.

14.1.2 Post-marketing experience with piperacillin and tazobactam for injection worldwide includes reports of the following drug-resistant bacterial infections:

- Methicillin-resistant Staphylococcus aureus
- Vancomycin-resistant Enterococcus
- Pseudomonas aeruginosa

14.1.3 Post-marketing experience with piperacillin and tazobactam for injection includes reports of serious skin reactions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported. These reactions are characterized by manifestations such as fever, rash, exfoliation of skin, and mucosal involvement. Other symptoms may include nausea, vomiting, diarrhea, and abdominal pain.

14.1.4 Post-marketing experience with piperacillin and tazobactam for injection includes reports of serious hematological reactions, such as thrombocytopenia, leukopenia, and agranulocytosis. These reactions are characterized by manifestations such as fever, headache, malaise, and bone pain. Other symptoms may include petechiae, purpuric skin lesions, and wound infections.

14.2.1 Post-marketing experience with piperacillin and tazobactam for injection includes reports of pseudomembranous colitis. This condition is characterized by urgency, rectal bleeding, and diarrhea. Other symptoms may include abdominal pain, cramping, and fever.

14.2.2 Post-marketing experience with piperacillin and tazobactam for injection includes reports of drug-resistant infections. These infections are characterized by manifestations such as fever, chills, and malaise. Other symptoms may include pain on motion, joint swelling, and tenderness.

14.2.3 Post-marketing experience with piperacillin and tazobactam for injection includes reports of allergic reactions, such as urticaria, rash, and pruritus. These reactions are characterized by manifestations such as itching, redness, and swelling. Other symptoms may include dyspnea, edema, and angioedema.

14.2.4 Post-marketing experience with piperacillin and tazobactam for injection includes reports of renal dysfunction. This condition is characterized by manifestations such as oliguria, anuria, and azotemia. Other symptoms may include pain on motion, joint swelling, and tenderness.
### Piperacillin and Tazobactam Injection

**Indications and Usage**

Piperacillin and Tazobactam injection is used to treat bacterial infections caused by susceptible strains of certain microorganisms. It is used to treat infections of the respiratory tract, urinary tract, skin and skin structure, bone, joint, and intra-abdominal infections. It is also used as a prophylactic agent in infected cardiac valve surgery and other invasive procedures.

**Dosage and Administration**

- **Adults:**
  - Single-dose vial provides piperacillin sodium equivalent to 3 grams of piperacillin and tazobactam sodium equivalent to 0.25 g of tazobactam. Each vial contains 4.7 mEq (108 mg) of sodium.
  - For administration by intravenous infusion over 30 minutes, the recommended dose is 2 g in the combination product. For use in adults with renal impairment, see the section on Dosage in Renal Impairment.

**Contraindications**

- Hypersensitivity to piperacillin or tazobactam.

**Warnings**

- **Gastrointestinal Perforation:** It is recommended that this medication be used with caution in patients with a history of gastrointestinal perforation.

**Adverse Reactions**

- **Gastrointestinal:** Nausea, vomiting, diarrhea, abdominal pain, and enterocolitis.

**Precautions**

- **Hepatobiliary Function:** Hepatic function should be monitored in patients with pre-existing liver disease.

**Usage in Special Populations**

- **Geriatric Use:** Use caution when administering this medication to geriatric patients, as this population is more susceptible to the side effects of antibiotics.

**Pharmacokinetics**

- Distribution Volume:
  - Population mean (SE) for piperacillin distribution volume is 12.6 L/kg. In the younger subjects, this parameter is 1.7 L/kg.

- Clearance:
  - Population mean (SE) for piperacillin clearance is 27.7 mL/min/kg. In the younger subjects, this parameter is 22.2 mL/min/kg.

- Protein Binding:
  - Protein binding of either piperacillin or tazobactam is not affected by the presence of plasma proteins.

**Interactions**

- **Drug Interactions:** This medication interacts with other drugs that may affect the serum level of piperacillin or tazobactam.

**Dosage in Renal Impairment**

- In patients with severe renal impairment, the dosage should be adjusted to prevent accumulation of the drug.

**Children**

- Use caution when administering this medication to children, as the safety and efficacy in this population have not been established.

**Antibiotic Susceptibility Testing**

- **Methods:** The standard dilution method is recommended for susceptibility testing.

- **Interpretation:** Interpretation of results of in vitro studies for bacteria should be considered within the context of the likely susceptibility of clinical isolates to therapeutic concentrations of the drug and the results of local control and susceptibility testing programs.

- **Quality Control Ranges:** The quality control ranges are based on a dilution method (broth or agar) or equivalent and are provided for reference only. The ranges for the quality control strains are provided in the table below.

---

**Table: Antibiotic Susceptibility Testing**

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Quality Control Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli</td>
<td>0.012 – 2</td>
</tr>
<tr>
<td>Klebsiella pneumonia</td>
<td>0.012 – 2</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>0.25 – 2</td>
</tr>
</tbody>
</table>

---

**Note:** This information is a summary and should not be considered a complete guide to the use of piperacillin and tazobactam. For more detailed information, consult the full prescribing information.