ampicillin for injection, USP
PHARMACY BULK PACKAGE - NOT FOR DIRECT INFUSION
Rx only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ampicillin and other antibacterial drugs, ampicillin should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION
Ampicillin for injection, USP is the monosodium salt of (2S,5S,6R)-6-[2-2-(2-Amino-1-carboxyethyl)amino]-3,3-dimethoxy-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, a synthetic penicillin. It is an antibacterial agent with a broad spectrum of bactericidal activity, against both penicillin-susceptible Gram-positive organisms and many common Gram-negative pathogens.

It has the following chemical structure:

\[
\text{CH}_2\text{CONH(COONa\text{H}_2)}
\]

The molecular formula is \( \text{C}_{16}\text{H}_{19}\text{NO}_{6}\text{S}\), and the molecular weight is 371.58.

Ampicillin for injection, USP contains 2.80 milligramm equivalents of sodium per 1 gram of drug.

Ampicillin for injection, USP is a white to off-white crystalline powder. The solution after constitution is clear and colorless.

Each Pharmacy Bulk Package bottle contains ampicillin sodium equivalent to 10 grams of ampicillin. The sodium content is 608.3 mg (26.6 mEq) per 10 grams of ampicillin.

The Pharmacy Bulk Package is a sterile dosage form which contains many single doses. The content of this Pharmacy Bulk Package is intended for use by a pharmacy or hospital pharmacist for the addition to parenteral fluids in the preparation of admixtures for intravenous infusion.

INDICATIONS AND USAGE
Ampicillin for injection, USP diffuses readily into most body tissues and fluids. However, penetration into cerebrospinal fluid is poor unless meninges are inflamed. Ampicillin is excreted rapidly unchanged in the urine and its excretion can be delayed by concurrent administration of probenecid. The active form appears in the bile in higher concentrations than those found in serum. Ampicillin is the least hydrolyzed of the penicillins and has been given in doses of 1 to 4 grams daily for many weeks without adverse reactions.

Microbiology
In vitro studies have demonstrated the susceptibility of most strains of the following organisms, clinical efficacy for infections other than those included in the INDICATIONS AND USAGE section have not been demonstrated.

The following bacteria have been shown in vitro to be susceptible to ampicillin:


GRAM-NEGATIVE ORGANISMS: Escherichia coli, Enterobacter aerogenes, Proteus mirabilis, Pseudomonas aeruginosa, indole-positive Klebsiella species, Citrobacter freundii, Neisseria gonorrhoeae, and Neisseria meningitidis.

Inhibitory concentrations of ampicillin for the following pathogens are usually less than 0.002 mcg/mL:

- most strains of Salmonella,
- Shigella, and
- E. coli

Ampicillin does not need destruction by penicillinase.

Susceptibility Tests
Ampicillin Susceptibility Test Discs, 10 mcg, should be used to estimate the in vitro susceptibility of bacteria to ampicillin.

INDICATIONS AND USAGE
Ampicillin for injection, USP is indicated for the treatment of infections caused by susceptible strains of the designated organisms in the following conditions:

Respiratory Tract Infections
- caused by Streptococcus pneumoniae (penicillin-susceptible), Hemophilus influenzae, and Moraxella catarrhalis (penicillin-resistant).
- caused by Haemophilus influenzae (penicillin-resistant).

Bacterial Meningitis
- caused by Neisseria meningitidis (Group B) and Streptococcus pneumoniae.

Septicaemia and Endocarditis
- caused by susceptible Gram-positive organisms including Streptococcus pyogenes, Staphylococcus aureus, and enterococci.
- caused by susceptible Gram-negative organisms including Escherichia coli and Klebsiella species.

Urinary Tract Infections
- caused by Escherichia coli and Proteus mirabilis.

Gastrointestinal infections
- caused by Salmonella typhi (typhoid fever), other Salmonella spp., and Shigella spp. (diarrhea) usually respond to oral or intravenous therapy.

Hepatitis
- caused by susceptible strains of Salmonella.

Urinary tract infections
- caused by susceptible strains of Escherichia coli and Proteus mirabilis.

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- caused by Salmonella typhi (typhoid fever), other Salmonella spp., and Shigella spp. (diarrhea) usually respond to oral or intravenous therapy.

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Labor and Delivery

Oral ampicillin-class antibiotics are poorly absorbed during labor. Studies in guinea pigs showed that intravenous administration of ampicillin slightly decreased the uterine tone and frequency of contractions, but markedly increased the height and duration of contractions. However, it is not known whether use of ampicillin-class antibiotics can cause fetal harm when administered to a pregnant woman. The decision to institute ampicillin-class antibiotics during labor should be based on whether the anticipated benefit outweighs the potential risk to the patient.

Ampicillin is excreted in small amounts in human milk. Therefore, caution should be exercised when ampicillin-class antibiotics are administered to a nursing woman.

Pediatric Use

Safeguards for the administration of these drugs to children are presented in "Dosage and Administration." ADVERSE REACTIONS

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They are rare, though they do occur, and they are generally reversible on discontinuation of therapy. They are more likely to occur in individuals who have previously demonstrated hypersensitivity reactions to ampicillin or to penicillins and in those with a history of allergy, asthma, hay fever, or urticaria.

The following adverse reactions have been reported as associated with the use of ampicillin:

Gastrointestinal

Nausea, diarrhea, black "jaundice" ranging, vomiting, enterocolitis, pseudomembranous colitis, and other reactions usually associated with sulfa drug intake.

Hypersensitivity Reactions

Nausea, vomiting, and itching have been reported infrequently. A few cases of idiosyncratic and anaphylactic reactions have been reported. Anaphylactic reactions are the most serious reaction experienced and has usually been immediately reversible on discontinuation of therapy. They are more likely to occur in individuals who have previously demonstrated hypersensitivity reactions to ampicillin or to penicillins and in those with a history of allergy, asthma, hay fever, or urticaria.

Note: Urticaria, other skin rashes, and serum sickness-like reactions may be controlled with antihistamines and aspirin. However, reactions occurring in patients who have demonstrated hypersensitivity should be considered evidence of allergy to ampicillin. Severe or recurrent reactions should be treated with corticosteroids. Patients should be warned that these reactions may be controlled with antihistamines but not precluded by their administration.

DOSE AND ADMINISTRATION

This is to be a Pharmacy Bulk Package and is intended for preparing IV admixtures only. Dosages of ampicillin for use in intravenous or intramuscular direct intravenous injections are for informational purposes only.

Infections of the respiratory tract and soft tissues.

Patients weighing less than 40 kg (88 lbs): 25 to 50 mg/kg/day in equally divided doses at 6- to 8-hour intervals.

Infections of the gastrointestinal and genitourinary tracts (including those caused by Neisseria gonorrhoeae and N. meningitidis).

Adults –

Two doses of 500 mg each at an interval of 8 to 12 hours. Treatment may be repeated if necessary or extended if required.

In the treatment of uncomplicated gonococcal or dysentery intussusceptions, 500 mg every 8 hours is recommended.

Children –

Dosage for children 100 to 200 mg/kg/day in equally divided doses every 3 to 4 hours. Treatment may be continued with intravenous drug therapy and continued with intramuscular injections. The doses for other infections may be given by either the intramuscular or intravenous route. A change to oral ampicillin may be made when appropriate.

Hematologic Abnormalities

Adolescents and children – 150 to 200 mg/kg/day in equally divided doses every 3 to 4 hours. Treatment may be continued with intravenous drug therapy and continued with intramuscular injections. For the doses for other infections may be given by either the intramuscular or intravenous route.

Hemolytic Anemia

Adolescents and children – 150 to 200 mg/kg/day. Start with intravenous administration for at least first few days and continue with the intramuscular route every 3 to 4 hours. Treatment of all infections should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes apheresis-negative. If additional autologous donations have been obtained, a minimum of 10 days’ treatment is recommended for any infection caused by Group A beta-hemolytic streptococci to help prevent the occurrence of acute rheumatic fever or acute glomerulonephritis.

For Administration by Intravenous Infusion – Reconstitute as directed below (see Directions for Proper Use of Pharmacy Bulk Package) prior to diluting with an intravenous solution.

IMPORTANT: This chemical stability information is no way indicates that it would be acceptable practice to use this product well after the preparation time. Good professional practice suggests that compounded admixtures should be administered as soon after preparation as is feasible. Stability studies on ampicillin sodium at several concentrations in various intravenous solutions indicate the drug will lose less than 10% of activity at the temperatures listed for the time periods stated.

Room Temperatures (20°C)

<table>
<thead>
<tr>
<th>Solution</th>
<th>Concentrations</th>
<th>Stability Periods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile Water for injection</td>
<td>up to 30 mg/mL</td>
<td>8 hours</td>
</tr>
<tr>
<td>Sodium Chloride Injection (USP) 0.9%</td>
<td>up to 30 mg/mL</td>
<td>8 hours</td>
</tr>
<tr>
<td>5% Dextrose in Water</td>
<td>up to 2 mg/mL</td>
<td>1 hour</td>
</tr>
<tr>
<td>5% Dextrose in Water</td>
<td>up to 2 mg/mL</td>
<td>2 hours</td>
</tr>
<tr>
<td>Lackland Ringer’s Solution</td>
<td>up to 10 mg/mL</td>
<td>1 hour</td>
</tr>
</tbody>
</table>

Refrigerated (5°C)

<table>
<thead>
<tr>
<th>Solution</th>
<th>Concentrations</th>
<th>Stability Periods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile Water for injection</td>
<td>30 mg/mL</td>
<td>48 hours</td>
</tr>
<tr>
<td>Sodium Chloride Injection (USP) 0.9%</td>
<td>up to 30 mg/mL</td>
<td>72 hours</td>
</tr>
<tr>
<td>5% Dextrose in Water</td>
<td>up to 2 mg/mL</td>
<td>24 hours</td>
</tr>
<tr>
<td>Sodium Chloride Injection (USP) 0.9%</td>
<td>up to 2 mg/mL</td>
<td>48 hours</td>
</tr>
<tr>
<td>Lackland Ringer’s Solution</td>
<td>up to 10 mg/mL</td>
<td>1 hour</td>
</tr>
</tbody>
</table>

The above solutions listed above should be used for the intravenous infusion of ampicillin for injection, USP. The concentrations shall fall within the range specified. The drug concentration and the rate of infusion should be adjusted so that the total dose of ampicillin is administered before the drug loses effectiveness.

Directions for Proper Use of Pharmacy Bulk Package:

This Pharmacy Bulk Package bottle contains ampicillin sodium equivalent 10 grams of ampicillin. It is designed for use in the pharmacy in preparing for admixtures using aseptic technique.

a) Add 94 mL Sterile Water for injection (USP). The resulting solution will contain 100 milligrams ampicillin activity per mL., and a stable up to 24 hours at room temperature.

b) Close vial and rotate for 1 minute. See Table for suitable final Use pH range. This chemical stability information is no way indicates that it would be acceptable practice to use this product well after the preparation time. Good professional practice suggests that compounded admixtures should be administered as soon after preparation as is feasible.

c) Using aseptic technique, the closure should be penetrated only once after recertification using a suitable sterile dispensing set, which should shown no discernible disintegration of the contents. Use of a syringe and needle is not recommended as a means of dispensing.

d) After entry, use entire contents of vial promptly. The entire contents of the Pharmacy Bulk Package must be dispensed within 24 hours after reconstitution. This time should begin with the introduction of solvent or diluent into the Pharmacy Bulk Package.

e) A pliable ball attached to the pharmacy bulk package provides a suitable hanging device while dispensing admixtures. Use of this product is restricted to a suitable work area, such as a laminar flow hood. Perfusion drug products with a concentration usually for particular matter and discretion prior to administration; whenever solution and container permit.

CAUTION: NOT TO BE DISPENSED AS A UNIT.

How Supplied

Ampicillin for injection USP Pharmacy Bulk Package bottle, 10 grams. The color of the dried powder is white or almost white crystalline solid, 100 mg per mL. See Table for suitable final Use pH range.

NDC: 50390-01

Ampicillin Sodium for Injection

USP

Store the dry powder at 35°C to 37°C (95°F to 100°F) or dilutions protected at 15°C to 30°C (59°F to 86°F) (see USP-United States Pharmacopoeia). 

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