AMPICILLIN SODIUM- ampicillin sodium injection, powder, for solution
Sagent Pharmaceuticals

Ampicillin for Injection, USP

PHARMACY BULK PACKAGE - NOT FOR DIRECT INFUSION

sagent®
Rx only

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

DESCRIPTION

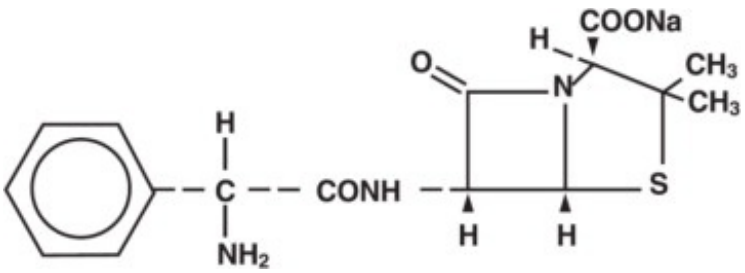
Ampicillin for Injection, USP the monosodium salt of [2S-[2α,5α,6β(S*)]]-6-[(aminophenylacetyl) amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0]heptane-2-carboxylic acid, is a synthetic penicillin for intravenous use. The pharmacy bulk package contains sterile ampicillin sodium equivalent to 10 grams ampicillin. 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.

Ampicillin for Injection, USP is a dry, white to off-white powder. The reconstituted solution is clear, colorless and free from visible particulates.

Each Pharmacy Bulk Package bottle contains ampicillin sodium equivalent to 10 grams of ampicillin. The sodium content is 65.8 mg (2.9 mEq) per one gram ampicillin.

A Pharmacy Bulk Package is a container of a sterile preparation for parenteral use that contains many single doses. The contents of this pharmacy bulk package are intended for use by a pharmacy admixture service for addition to suitable parenteral fluids in the preparation of admixtures for intravenous infusion. (see **DOSAGE AND ADMINISTRATION, *Directions for Proper Use of Pharmacy Bulk Package***).

It has the following molecular structure:



The molecular formula is $C_{16}H_{18}N_3NaO_4S$, and the molecular weight is 371.39. The pH range of the reconstituted solution is 8 to 10.

CLINICAL PHARMACOLOGY

Ampicillin for Injection, USP diffuses readily into most body tissues and fluids. However, penetration into the cerebrospinal fluid and brain occurs only when the meninges are inflamed. Ampicillin is excreted largely unchanged in the urine and its excretion can be delayed by concurrent administration of probenecid. Due to maturational changes in renal function, ampicillin half-life decreases as postmenstrual age (a sum of gestational age and postnatal age) increases for infants with postnatal age of less than 28 days. The active form appears in the bile in higher concentrations than those found in serum. Ampicillin is the least serum-bound of all the penicillins, averaging about 20% compared to approximately 60 to 90% for other penicillins. Ampicillin for Injection, USP is well tolerated by most patients and has been given in doses of 2 grams daily for many weeks without adverse reactions.

Microbiology

While *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 has not been demonstrated.

Antibacterial Activity

The following bacteria have been shown in *in vitro* studies to be susceptible to Ampicillin for Injection, USP:

Gram-positive Bacteria

Hemolytic and nonhemolytic *streptococci*

Streptococcus pneumoniae

Nonpenicillinase-producing *staphylococci*

Clostridium spp.

B. anthracis

Listeria monocytogenes

Most strains of *enterococci.*

Gram-negative Bacteria

H. influenzae

N. gonorrhoeae

N. meningitidis

Proteus mirabilis

Many strains of *Salmonella*, *Shigella*, and *E. coli*.

AMPICILLIN does not resist destruction by penicillinase.

Susceptibility Testing

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: https://www.fda.gov/STIC.

INDICATIONS AND USAGE

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

Respiratory Tract Infections caused by *Streptococcus pneumoniae, Staphylococcus aureus* (penicillinase and nonpenicillinase-producing), *H. influenzae*, and Group A beta-hemolytic *streptococci*.

Bacterial Meningitis caused by *E. coli,* Group B *Streptococci*, and other Gram-negative bacteria (*Listeria monocytogenes, N. meningitidis*). The addition of an aminoglycoside with ampicillin may increase its effectiveness against Gram-negative bacteria.

Septicemia and Endocarditis caused by susceptible Gram-positive organisms including *Streptococcus* spp., penicillin G-susceptible *staphylococci*, and *enterococci*. Gram-negative sepsis caused by *E. coli*, *Proteus mirabilis* and *Salmonella* spp. responds to ampicillin. Endocarditis due to enterococcal strains usually respond to intravenous therapy. The addition of an aminoglycoside may enhance the effectiveness of ampicillin when treating streptococcal endocarditis.

Urinary Tract Infections caused by sensitive strains of *E. coli* and *Proteus mirabilis*.

Gastrointestinal Infections caused by *Salmonella typhi* (typhoid fever), other *Salmonella* spp., and *Shigella* spp. (dysentery) usually respond to oral or intravenous therapy.

Bacteriology studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Therapy may be instituted prior to obtaining results of susceptibility testing. It is advisable to reserve the parenteral form of this drug for moderately severe and severe infections and for patients who are unable to take the oral forms. A change to oral ampicillin may be made as soon as appropriate.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ampicillin for Injection, USP and other antibacterial drugs, Ampicillin for Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Indicated surgical procedures should be performed.

CONTRAINDICATIONS

A history of a previous hypersensitivity reaction to any of the penicillins is a contraindication.

WARNINGS

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more apt to occur in individuals with a history of penicillin hypersensitivity

and/or a history of sensitivity to multiple allergens. There have been well-documented reports of individuals with a history of penicillin hypersensitivity reactions who have experienced severe hypersensitivity reactions when treated with a cephalosporin. Before initiating therapy with a penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, and other allergens. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy instituted.

SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE, OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS INDICATED.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including ampicillin for injection, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS

General

The possibility of superinfections with mycotic organisms or bacterial pathogens should be kept in mind during therapy. In such cases, discontinue the drug and substitute appropriate treatment.

A high percentage (43 to 100 percent) of patients with infectious mononucleosis who receive ampicillin develop a skin rash. Typically, the rash appears 7 to 10 days after the start of oral ampicillin therapy and remains for a few days to a week after the drug is discontinued. In most cases, the rash is maculopapular, pruritic, and generalized. Therefore, the administration of ampicillin is not recommended in patients with mononucleosis. It is not known whether these patients are truly allergic to ampicillin.

Prescribing Ampicillin for Injection, USP in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Information for Patients

Patients should be counseled that antibacterial drugs including Ampicillin for Injection, USP should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Ampicillin for Injection, USP is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early

in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may: (1) decrease the effectiveness of the immediate treatment, and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Ampicillin for Injection, USP or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Laboratory Tests

As with any potent drug, periodic assessment of organ system function, including renal, hepatic, and hematopoietic, should be made during prolonged therapy.

Transient elevation of serum transaminase has been observed following administration of ampicillin. The significance of this finding is not known.

Drug Interactions

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of skin rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients.

Drug/Laboratory Test Interactions

With high urine concentrations of ampicillin, false- positive glucose reactions may occur if Clinitest, Benedict's Solution, or Fehling's Solution are used. Therefore, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix or Tes-Tape) be used.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

No long-term animal studies have been conducted with this drug.

Pregnancy

Reproduction studies have been performed in laboratory animals at doses several times the human dose and have revealed no evidence of adverse effects due to ampicillin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

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 moderately increased the height and duration of contractions. However, it is not known whether use of these drugs in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood that forceps delivery or other obstetrical

intervention or resuscitation of the newborn will be necessary.

Nursing Mothers

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

Pediatric Use

Guidelines for the administration of these drugs to children, including neonates are presented in **DOSAGE AND ADMINISTRATION** section.

ADVERSE REACTIONS

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They are more likely to occur in individuals who have previously demonstrated hypersensitivity 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

Glossitis, stomatitis, black “hairy” tongue, nausea, vomiting, enterocolitis, pseudomembranous colitis, and diarrhea. (These reactions are usually associated with oral dosage forms.)

Hypersensitivity Reactions

Skin rashes and urticaria have been reported frequently. A few cases of exfoliative dermatitis and erythema multiforme have been reported. Linear IgA bullous dermatosis has been reported. Anaphylaxis is the most serious reaction experienced and has usually been associated with the parenteral dosage form.

Note: Urticaria, other skin rashes, and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, ampicillin should be discontinued, unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to ampicillin therapy. Serious anaphylactic reactions require the immediate use of epinephrine, oxygen, and intravenous steroids.

Liver - A moderate rise in serum glutamic oxaloacetic transaminase (SGOT) has been noted, particularly in infants, but the significance of this finding is unknown. Mild transitory SGOT elevations have been observed in individuals receiving larger (two to four times) than usual and oft-repeated intramuscular injections. Evidence indicates that glutamic oxaloacetic transaminase (GOT) is released at the site of intramuscular injection of ampicillin sodium and that the presence of increased amounts of this enzyme in the blood does not necessarily indicate liver involvement.

Hemic and Lymphatic Systems - Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported during therapy with the penicillins. These reactions are usually reversible on discontinuation of

therapy and are believed to be hypersensitivity phenomena.

Central Nervous System - Seizures

To report SUSPECTED ADVERSE REACTIONS, contact Sagent Pharmaceuticals at 1-866-625-1618 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

In cases of overdose, discontinue medication, treat symptomatically, and institute supportive measures as required. In patients with renal function impairment, ampicillin-class antibiotics can be removed by hemodialysis but not peritoneal dialysis.

DOSAGE AND ADMINISTRATION

This insert is for a Pharmacy Bulk Package and is intended for preparing intravenous admixtures only. Dosage recommendations for intramuscular or direct intravenous injection are for informational purposes only.

Infections of the respiratory tract and soft tissues.

Patients weighing 40 kg (88 lbs) or more: 250 mg to 500 mg every 6 hours.

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* in females).

Patients weighing 40 kg (88 lbs) or more: 500 mg every 6 hours.

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

In the treatment of chronic urinary tract and intestinal infections, frequent bacteriological and clinical appraisal is necessary. Smaller doses than those recommended above should not be used. Higher doses should be used for stubborn or severe infections. In stubborn infections, therapy may be required for several weeks. It may be necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy.

Urethritis in males due to *N. gonorrhoeae.*

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 complications of gonorrheal urethritis, such as prostatitis and epididymitis, prolonged and intensive therapy is recommended. Cases of gonorrhea with a suspected primary lesion of syphilis should have darkfield examinations before receiving treatment. In all other cases where concomitant syphilis is suspected, monthly serological tests should be made for a minimum of four months.

The doses for the preceding infections may be given by either the intramuscular or intravenous route. A change to oral ampicillin may be made when appropriate.

Bacterial Meningitis

Adults and children - 150 to 200 mg/kg/day in equally divided doses every 3 to 4 hours. (Treatment may be initiated with intravenous drip therapy and continued with intramuscular injections.) The doses for other infections may be given by either the intravenous or intramuscular route.

Neonates (less than or equal to 28 days of postnatal age) - Dosage should be based on Gestational age and Postnatal age according to **Table 1.**

TABLE 1: Dosage in Neonates (less than or equal to 28 days of postnatal age) for Bacterial Meningitis and Septicemia

Gestational age (weeks)	Postnatal age (days)	Dosage
less than or equal to 34	less than or equal to 7	100 mg/kg/day in equally divided doses every 12 hours
less than or equal to 34	greater than or equal to 8 and less than 28	150 mg/kg/day in equally divided doses every 12 hours
greater than 34	less than or equal to 28	150 mg/kg/day in equally divided doses every 8 hours

Septicemia

Adults and children: 150 to 200 mg/kg/day. Start with intravenous administration for at least three days and continue with the intramuscular route every 3 to 4 hours.

Neonates (less than or equal to 28 days of postnatal age) - Dosage should be based on Gestational age and Postnatal age according to **Table 1** (above).

Treatment of all infections should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has 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.

DIRECTIONS FOR USE

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 in 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% activity at the temperatures noted for the time periods stated.

Room Temperature (25°C)		
Diluent	**Concentrations**	**Stability Periods**

Sterile Water for Injection, USP	up to 30 mg/mL	8 hours
0.9% Sodium Chloride Injection, USP	up to 30 mg/mL	8 hours
5% Dextrose Injection, USP	10 to 20 mg/mL	1 hour
5% Dextrose Injection, USP	up to 2 mg/mL	2 hours
5% Dextrose and 0.45% NaCl Injection, USP	up to 2 mg/mL	2 hours
Lactated Ringer's Injection, USP	up to 30 mg/mL	8 hours
Refrigerated (4°C)		
Sterile Water for Injection, USP	30 mg/mL	48 hours
Sterile Water for Injection, USP	up to 20 mg/mL	72 hours
0.9% Sodium Chloride Injection, USP	30 mg/mL	24 hours
0.9% Sodium Chloride Injection, USP	up to 20 mg/mL	48 hours
Lactated Ringer's Injection, USP	up to 30 mg/mL	24 hours
5% Dextrose Injection, USP	up to 20 mg/mL	1 hour
5% Dextrose and 0.45% NaCl Injection, USP	up to 10 mg/mL	1 hour

Only those solutions listed above should be used for the intravenous infusion of Ampicillin for Injection, USP. The concentrations should fall within the range specified. The drug concentration and the rate and volume of the infusion should be adjusted so that the total dose of ampicillin is administered before the drug loses its stability in the solution in use.

Directions for Proper Use of Pharmacy Bulk Package

This Pharmacy Bulk Package glass bottle contains ampicillin sodium equivalent to 10 grams of ampicillin. It is designed for use in the pharmacy in preparing intravenous admixtures using aseptic technique in a laminar flow hood.

a) Add 94 mL Sterile Water for Injection, USP. The resulting solution will contain 100 milligrams ampicillin activity per mL, and is stable up to **1 HOUR** at room temperature.
b) Dilute further within **1 HOUR** to a concentration of 5 mg to 10 mg per mL. See Table for suitable fluid. Use promptly. This chemical stability information in no way indicates that it would be acceptable practice to use this product well after preparation time. Good professional practice suggests that compounded admixtures should be administered as soon after preparation as is feasible.
c) Using aseptic technique under a laminar flow hood, the closure should be penetrated only one time after reconstitution using a suitable sterile dispensing set; which allows measured dispensing of the contents. Use of a syringe and needle is not recommended as it may cause leakage.
d) After entry, use entire contents of bottle promptly. The entire contents of the Pharmacy Bulk Package must be dispensed within **1 HOUR** of reconstitution. This time limit should begin with the introduction of solvent or diluent into the Pharmacy Bulk Package.

Use of this product is restricted to a suitable work area, such as a laminar flow hood. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

CAUTION: NOT TO BE DISPENSED AS A UNIT.

HOW SUPPLIED

Ampicillin for Injection, USP is supplied as follows:

NDC	Ampicillin for Injection, USP	Package Factor
25021-197-99	10 gram Pharmacy Bulk Bottle	1 bottle per carton

Each Ampicillin for Injection, USP Pharmacy Bulk Package bottle contains ampicillin sodium equivalent to 10 grams of ampicillin.

Storage Conditions

Store dry powder at 20º to 25ºC (68º to 77ºF). [See USP Controlled Room Temperature.]

Protect the constituted solution from freezing.

Sterile, Nonpyrogenic, Preservative-free.
The container closure is not made with natural rubber latex.

Clinitest is a registered trademark of Miles, Inc.
Clinistix is a registered trademark of Bayer Corporation.
Tes-Tape is a registered trademark of Eli Lilly Company.

sagent®
Mfd. for SAGENT Pharmaceuticals
Schaumburg, IL 60173 (USA)
Made in Italy
©2025 Sagent Pharmaceuticals

Revised: September 2025

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – Bottle Label

NDC 25021-197-99

Rx only

Ampicillin for Injection, USP

10 grams per Pharmacy Bulk Package

PHARMACY BULK PACKAGE

NOT FOR DIRECT INFUSION

NOT TO BE DISPENSED AS A UNIT

For Intravenous Use

One 10 gram Pharmacy Bulk Package Bottle

AMPICILLIN SODIUM

ampicillin sodium injection, powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:25021-197
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Ampicillin Sodium (UNII: JFN36L5S8K) (Ampicillin - UNII:7C782967RD)	Ampicillin	10 g in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:25021-197-99	1 in 1 CARTON	01/15/2025	
1		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201404	01/15/2025	

Labeler - Sagent Pharmaceuticals (080579617)