PRESCRIBING INFORMATION

PrAMPICILLIN FOR INJECTION, USP

250 mg, 500 mg, 1,000 mg, 2,000 mg, and 10,000 mg per vial

ampicillin (as ampicillin sodium)

Sterile

Antibiotic

SteriMax Inc.
2770 Portland Drive,
Oakville, ON
L6H 6R4

Date of Revision:
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Control #: 284096

[Pr]AMPICILLIN FOR INJECTION, USP
Antibiotic

Actions and Clinical Pharmacology:

Ampicillin has a broad spectrum of bactericidal activity against many gram-positive and gram-negative aerobic and anaerobic bacteria. It acts through the inhibition of cell wall mucopeptide biosynthesis during the stage of active multiplication.

Indications and Clinical Use:

The treatment of infections due to susceptible gram negative organisms (including strains of shigellae, *S. typhosa* and other salmonellae, *E. coli, H. influenzae,* and *P. mirabilis*) and susceptible gram positive organisms (including streptococci, pneumococci, and non-beta-lactamase (penicillinase) producing staphylococci). Infections of the ear, nose, throat and lower respiratory tract.

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 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.

Contraindications:

A history of allergic reactions to penicillin or cephalosporins.

Warnings:

Before therapy, inquiry as to past penicillin or other allergies is essential as reactions occur more frequently in hypersensitive persons. During therapy, if allergic or anaphylactic reactions occur, discontinue treatment and initiate usual measures, i.e. antihistamines, pressor amines or corticosteroids. During long-term therapy, renal, hepatic, and hematopoietic functions should be checked periodically. Candidiasis and other superinfections may occur, especially in debilitated and malnourished patients, or those with low resistance to infection due to corticosteroids, immunosuppressors or irradiation.

The passage of any penicillin from blood into brain is facilitated by inflamed meninges and during cardiopulmonary bypass. In the presence of such factors and particularly in the presence of renal failure when high serum concentrations can be attained, central nervous system adverse effects including myoclonus, convulsive seizures and depressed consciousness can be expected. Although this complication has not been reported with ampicillin, it should be anticipated.

Severe Cutaneous Adverse Reactions

Severe cutaneous adverse reactions (SCAR) such as acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with betalactam treatment When SCAR is suspected, AMPICILLIN FOR INJECTION, USP should be discontinued and appropriate therapy and/or measures should be taken.

Precautions:

General: A high percentage of patients with infectious mononucleosis or lymphatic leukemia who receive ampicillin develop a skin rash, and the drug should not be administered to such patients. In most cases, the rash is maculopapular, pruritic, and generalized.

Prolonged use of antibiotics may promote overgrowth of nonsusceptible organisms. Should superinfections occur, appropriate measures should be taken.

Susceptibility/Resistance
Development of Drug Resistant Bacteria
Prescribing AMPICILLIN FOR INJECTION, USP in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of resistant organisms.

Drug Interactions:

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of 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 to hyperuricemia present in these patients. Ampicillin and aminoglycosides should not be reconstituted together due to the in vitro inactivation of the aminoglycosides by the ampicillin.

Drug/Laboratory Test Interactions: Following administration of ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone and estradiol has been noted.

With high urine concentrations of ampicillin, false-positive urinary glucose reactions may occur if copper reduction methods are used. Therefore, it is recommended that glucose tests based on enzymatic glucose oxidase reactions be employed.

Pregnancy: Animal studies with ampicillin have shown no teratogenic effects. 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.

Lactation: Ampicillin is excreted in trace amounts in human milk. Therefore, caution should be exercised when ampicillin is administered to a nursing mother.

Use in Elderly: There are no known specific precautions for the use of ampicillin in the elderly.

Adverse Reactions

Gastrointestinal Disturbances: glossitis, stomatitis, black “hairy” tongue, nausea, vomiting, diarrhea, enterocolitis and pseudomembranous colitis. (These reactions are usually associated with oral administration.)

Hypersensitivity Reactions: Erythematous maculopapular rashes have been reported fairly frequently; uriticaria, erythema multiforme, and a few cases of exfoliative dermatitis have been observed. Anaphylaxis is the most serious reaction usually associated with parenteral administration.

Note: Uriticaria, other skin rashes, and serum sickness like reactions may be controlled with antihistamines, and if necessary, systemic corticosteroids. Serious anaphylactic reactions require the immediate use of epinephrine, oxygen and i.v. corticosteroids. In cases of infectious mononucleosis, where ampicillin has been administered, an extremely high incidence of generalized rash has been reported.

Renal: Interstitial nephritis has been reported.

Ototoxicity: Ampicillin may be ototoxic when given i.v. in very high doses.

Hepatic: A mild transitory elevation of serum glutamic oxaloacetic transaminase (SGOT) in individuals receiving large (2 to 4 times recommended dose) and often repeated i.m. injections. Evidence indicates that serum glutamic oxaloacetic transaminase (SGOT) is released at the site of i.m. injection of sodium ampicillin and that the presence of the enzyme in the blood does not necessarily indicate liver involvement.

Hematologic Disturbances: Anemia, thrombocytopenia, thrombocytopenic purpura, hemorrhagic diathesis, eosinophilia, leukopenia and agranulocytosis have been reported rarely in association with ampicillin therapy. These reactions are usually reversible on discontinuation of the drug and are believed to be hypersensitivity phenomena.

Symptoms and Treatment of Overdosage

The treatment of overdosage would likely be needed only in patients with severely impaired renal function. In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures as required. In patients with renal function impairment, ampicillinclass antibiotics can be removed by hemodialysis but not by peritoneal dialysis.

Dosage and Administration

Dosage:
Infections of the ear, nose, throat and lower respiratory tract:
Adults: 250 to 500 mg every 6 hours.
Children: 25 to 50 mg/kg/day in equally divided doses at 6-hour intervals.

Infections of gastrointestinal tract and of the genitourinary tract:
Adults: 500 mg every 6 hours.
Children: 50 mg/kg/day in equally divided doses at 6-hour intervals.

Larger doses may be required for stubborn or severe infections. The children's dosages are intended for individuals whose weights will not result in calculated dosage greater than that recommended for adults.

In the treatment of chronic urinary tract and intestinal tract infections, frequent bacteriological and clinical appraisal is necessary. Smaller doses than those recommended above should not be used; higher doses may be needed at times. 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.

Treatment 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 betahemolytic streptococci. In gonorrhea therapy, serologic tests for syphilis should be performed initially and monthly for 3 months.

Administration:
IM/Direct IV Use: Entire contents should be withdrawn and the dose injected over a period of 3-5 minutes.

IV Infusion: Entire contents should be withdrawn and the dose injected over a period of at least 10-15 minutes.

CAUTION: More rapid administration may result is convulsive seizures. The solution must be used within 1 hour after reconstitution.

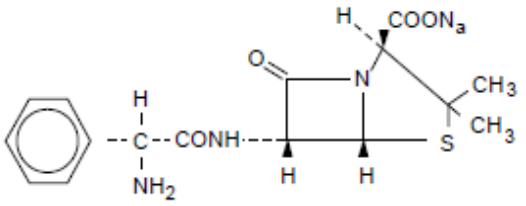
Pharmaceutical Information

Drug Substance:

Name: ampicillin sodium

Chemical Name: Sodium (2S, 5R, 6R)-6-[[(2R)-2-amino-2-phenylacetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate

Structural Formula:



Molecular Formula: $C_{16}H_{18}NaN_3O_4S$

Molecular Weight: 371.4 g/mol (anhydrous)

Description: Ampicillin sodium is a white to off-white crystalline powder. It is freely soluble, sparingly soluble in acetone practically insoluble in fatty oils and in liquid paraffin.

Composition: Each vial contains 250 mg, 500 mg, 1,000 mg, 2,000 mg or 10,000 mg of ampicillin base as the sodium salt. Each gram of ampicillin sodium for injection contains approximately 2.6 mEq of sodium.

Stability & Storage Recommendations: Store the dry powder at controlled room temperature not exceeding 25 °C.

Reconstituted Solutions: Use sterile water for injection as the only diluent.
Reconstituted solutions should be used within 1 hour when kept at controlled room temperature not exceeding 25 °C. Protect reconstituted solutions from freezing.

Reconstitution

I.M. Use: Using sterile water for injection, reconstitute as follows:

Vial Size (mg)	Volume of Diluent Added (mL)	Withdrawable Volume (mL)	Nominal Concentration (mg/mL)
250	1.9	2.0	125

500	1.8	2.0	250
1000	3.5	4.0	250

Withdraw the entire contents and use within 1 hour after reconstitution.

Direct I.V. Use: Use sterile water for injection, reconstitute as follows:

Vial Size (mg)	Volume of Diluent Added (mL)	Withdrawable Volume (mL)	Nominal Concentration (mg/mL)
250	1.9	2.0	125
500	1.8	2.0	250

For direct intravenous administration, the product should be diluted to a concentration of 50 mg/mL with Sterile Water for Injection and administered by slow injection (three to four minutes).

Withdraw the entire contents and use within 1 hour after reconstitution.

I.V. Infusion: Use sterile water for injection for initial dilution of the 1000 mg and 2000 mg vials, and reconstitute as follows:

Vial Size (mg)	Volume of Diluent Added (mL)	Withdrawable Volume (mL)	Nominal Concentration (mg/mL)
1000	3.5	4.0	250
2000	6.8	8.0	250

Withdraw the entire contents and use within 1 hour after reconstitution.

Pharmacy Bulk Vial
Add 94 mL sterile Water for Injection. The resulting solution will contain 100 mg ampicillin activity per mL and is stable up to 1 hour at room temperature.

Dilute further within 1 hour with an appropriate IV solution to a final concentration as outlined in the following paragraph.

Parenteral Products: Stability studies on ampicillin sodium, at concentrations of 2 mg/mL and 30 mg/mL in various i.v. solutions, indicate the drug will lose less than 10% activity at room temperature (22°C) for the time periods stated when the drug is added to the following infusion fluids:

Isotonic Sodium Chloride	(30 mg/mL)	8 hours
5% Dextrose in water	(2 mg/mL)	4 hours

5% Dextrose in 0.4% Sodium Chloride solution	(2 mg/mL)	4 hours
10% Invert sugar in water	(2 mg/mL)	4 hours
M/6 Sodium Lactate solution	(30 mg/mL)	4 hours

Availability of Dosage Forms: AMPICILLIN FOR INJECTION, USP is supplied as a dry powder in vials containing: 250 mg, 500 mg, 1,000 mg, 2,000 mg or 10,000 mg of ampicillin base as the sodium salt.

Bibliography

1. Ampicillin Sodium for Injection, USP, submission control number: 281284, Prescribing Information, Teva Canada Ltd. Apr 11, 2024

PATIENT MEDICATION INFORMATION

PrAMPICILLIN FOR INJECTION, USP
(ampicillin sodium)

Read this carefully before you start taking AMPICILLIN FOR INJECTION, USP and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about AMPICILLIN FOR INJECTION, USP.

What is AMPICILLIN FOR INJECTION, USP used for:
AMPICILLIN FOR INJECTION, USP is used to treat certain infections of the:

- Ear
- Nose
- Throat
- Lower Respiratory tract
- Antibacterial drugs like AMPICILLIN FOR INJECTION, USP treat only bacterial infections. They do not treat viral infections.

How does AMPICILLIN FOR INJECTION, USP work?
AMPICILLIN FOR INJECTION, USP is an antibiotic that works by:

- Stopping the growth of bacteria.
- Killing bacteria.

What are the ingredients in AMPICILLIN FOR INJECTION, USP?
Medicinal ingredients: Ampicillin Sodium
Each gram of ampicillin sodium for injection contains approximately 60 mg, or approximately 6-8% sodium.

AMPICILLIN FOR INJECTION, USP comes in the following dosage forms:
AMPICILLIN FOR INJECTION, USP is supplied as a dry powder in vials containing: 250 mg, 500 mg, 1,000 mg, 2,000 mg or 10,000mg of ampicillin base as the sodium salt.

Do not use AMPICILLIN FOR INJECTION, USP if:

- You have had an allergic reaction to AMPICILLIN FOR INJECTION, USP or other medicines such as cephalosporins or penicillins.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AMPICILLIN FOR INJECTION, USP. Talk about any health conditions or problems you may have, including if you:

- Have severe kidney disease with or without significant liver disease
- Are pregnant or planning to become pregnant
- Are breast feeding or planning to breastfeed.

Other warnings that you should know:

AMPICILLIN FOR INJECTION, USP may affect certain urine test results. Remind your healthcare professional that you are taking AMPICILLIN FOR INJECTION, USP if a urine test is ordered.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with AMPICILLIN FOR INJECTION, USP:

- Allopurinol, used to treat gout or kidney stones

How to take AMPICILLIN FOR INJECTION, USP:

- Although you may feel better early in treatment, AMPICILLIN FOR INJECTION, USP should be used exactly as directed.
- Misuse or overuse of AMPICILLIN FOR INJECTION, USP could lead to the growth of bacteria that will not be killed by AMPICILLIN FOR INJECTION, USP (resistance). This means that AMPICILLIN FOR INJECTION, USP may not work for you in the future.
- Do not share your medicine.

Usual Dose:

Adults: Your doctor will decide your dose based on your infection. The usual dose is 250 mg – 500 mg every 6 hours.

Children: Your doctor will decide your child's dose based on your child's weight and their infection.

Overdose:

If you think you have taken too much AMPICILLIN FOR INJECTION, USP, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using AMPICILLIN FOR INJECTION, USP?

These are not all the possible side effects you may feel when taking AMPICILLIN FOR INJECTION, USP. If you experience any side effects not listed here, contact your healthcare professional.

- Upper stomach pain
- Flatulence

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor for any side effect that seems unusual or that is especially bothersome.

Serious side effects and what to do about them:

Symptom/effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	

Rare	an allergic reaction (difficulty in breathing, closing of the throat, swelling of the lips, face or tongue; hives or a rash)			✓
	redness, or itching			✓
	severe nausea, vomiting, or diarrhea			✓
	Severe Cutaneous Adverse Reactions (SCAR) (severe skin reactions that may also affect other organs): • Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • Swelling and redness of eyes or face • Flu-like feeling, fever, chills, body aches, swollen glands, cough • Shortness of breath, chest pain or discomfort			✓

This is not a complete list of side effects. For any unexpected effects while taking AMPICILLIN FOR INJECTION, USP, contact your doctor or pharmacist.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

How to store AMPICILLIN FOR INJECTION, USP:
Dry Powder: Store the dry powder at controlled room temperature not exceeding 25°C.

Reconstituted Solutions: Use sterile water for injection as the only diluent.

Reconstituted solutions should be used within 1 hour when kept at controlled room temperature not exceeding 25°C. Protect reconstituted solutions from freezing.
Keep out of reach and sight of children.

If you want more information about AMPICILLIN FOR INJECTION, USP:

- Talk to your healthcare professional
- Find the full Prescribing Information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.sterimaxinc.com, or by calling 1-800-881-3550.

This leaflet was prepared by:

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