

**PRESCRIBING INFORMATION**  
**INCLUDING PATIENT MEDICATION INFORMATION**

**Pr Ampicillin For Injection, USP**

Powder for solution

250 mg, 500 mg, 1 g and 2 g per vial

For Intramuscular or Intravenous Use

**Sterile**

**Antibiotic**

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## **PRESCRIBING INFORMATION**

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## **PHARMACOLOGICAL CLASSIFICATION**

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].

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 penicillins 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.

## **PRECAUTIONS**

The safety of this drug in pregnancy has not been established.

### **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.

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

## **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: urticaria, erythema multiforme, and a few cases of exfoliative dermatitis have been observed. Anaphylaxis is the most serious reaction usually associated with parenteral administration.

Urticaria, 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 intravenous corticosteroids. In cases of infectious mononucleosis, where ampicillin has been administered, an extremely high incidence of generalized rash has been reported.

### **Hepatic**

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

### **Hematologic Disturbances**

Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and agranulocytosis have been reported. These 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.

## **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 the 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 rinses 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 beta-hemolytic streptococci.

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

### **Reconstituted Solutions**

ASEPTIC TECHNIQUES SHOULD BE USED.

Use Sterile Water for Injection as the only diluent.

Reconstituted solutions should be used within one hour when kept at controlled room temperature between 15 °C and 30 °C, since the potency may decrease significantly. Protect reconstituted solutions from freezing.

**Intramuscular:** Using Sterile Water for Injection, Ampicillin for Injection, USP may be reconstituted as follows (see Table 1):

**Table 1: Reconstitution for Intramuscular Use**

<u>Vial Size</u>	<u>Diluent Added</u>	<u>Approximate Withdrawable Volume</u>	<u>Approximate Concentration Per mL</u>
250 mg	0.9 mL	1 mL	250 mg
500 mg	1.8 mL	2 mL	250 mg
1 g	3.4 mL	4 mL	250 mg
2 g	6.8 mL	8 mL	250 mg

**Direct intravenous use:** Use Sterile Water for Injection. Add 5 mL to the 250 mg or 500 mg vial, withdraw contents, and administer slowly over a period of 3 to 5 minutes. Add 7.4 mL to the 1 g vial and withdraw the entire contents (see Table 2). Inject slowly over a period of at least 10 to 15 minutes. **CAUTION:** More rapid administration may result in convulsive seizures.

**Table 2: Reconstitution for Intravenous Use**

<u>Vial Size</u>	<u>Diluent Added</u>	<u>Approximate Withdrawable Volume</u>	<u>Approximate Concentration Per mL</u>
250 mg	5 mL	5 mL	50 mg
500 mg	5 mL	5 mL	100 mg
1 g	7.4 mL	8 mL	125 mg
2 g	10 mL	11 mL	180 mg

**Intravenous Infusion:** Reconstitute the 1g or 2 g vial with 7.4 mL or 10 mL respectively, of Sterile Water for Injection prior to dilution to the desired volume with one of the intravenous solutions listed below. Stability studies at concentrations of 2 mg/mL and 30 mg/mL in various intravenous solutions, indicate the drug will lose less than 10% activity at room temperature (between 15 °C and 30 °C) for the time periods stated (see Table 3). Unused portions should be discarded after the time period indicated.

**Table 3**

<b><u>Diluent</u></b>	<b><u>Concentration</u></b>	<b><u>Stability Periods</u></b>
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	8 hours

The drug concentration and the rate and volume of infusion should be adjusted so that the total dose of ampicillin is administered before the drug loses its stability in the solution in use.

Parenteral products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

### **COMPOSITION**

Each vial of Ampicillin for Injection, USP contains 250 mg, 500 mg, 1 g, or 2 g of ampicillin as the sodium salt. Each gram of ampicillin sodium contains approximately 60 mg or approximately 6% sodium.

### **STABILITY AND STORAGE RECOMMENDATIONS**

Store the dry powder at controlled room temperature between 15 °C and 30 °C.

### **AVAILABILITY OF DOSAGE FORMS**

Ampicillin for Injection, USP is supplied as a dry powder in vials containing 250 mg, 500 mg, 1 g and 2 g of ampicillin as ampicillin sodium.

## REFERENCES

1. AMPICILLIN SODIUM FOR INJECTION, USP, Prescribing Information, Teva Canada Limited, version December 17, 2018, Control # 216284.

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE****PATIENT MEDICATION INFORMATION****Pr Ampicillin for Injection, USP  
Powder of solution****Sterile**

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 bacterial infections.

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% 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 g and 2 g of ampicillin as ampicillin sodium.

**Do not use Ampicillin for Injection, USP if:**

- You have had an allergic reaction to ampicillin or other medicines such as penicillins or cephalosporins.

**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 any allergies**
- 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:**

Your healthcare provider will give you your daily dose of 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. The usual dose is 25 to 50 mg/kg/day in equally divided doses every 6 hours.

**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.

Side Effects Include:

- Black “hairy” tongue
- Upper stomach pain

**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	
<b>Rare</b>	Allergic reaction: difficulty in breathing, closing of the throat, swelling of the lips, face or tongue; hives or a rash			√
	Fever, joint pain, rash, swelling and nausea		√	
	Severe nausea, vomiting, or diarrhea			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**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.*

**Storage:**

**Dry Powder:** Store the dry powder at controlled room temperature between 15 °C and 30 °C.

**Reconstituted Solutions:**

Reconstituted solutions should be used within one hour when kept at controlled room temperature between 15 °C and 30 °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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); Fresenius Kabi Canada's website (<http://www.fresenius-kabi.com/en-ca/>), or by calling 1-877-821-7724.

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