Amoxicillin for Injection, USP
Rx Only
FOR INTRAMUSCULAR OR INTRAVENOUS USE

INDICATIONS AND USAGE

Ampicillin for Injection, USP is indicated in the treatment of infections caused by susceptible strains of the following microorganisms: Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus faecalis, Staphylococcus aureus, Staphylococcus saprophyticus, Streptococcus agalactiae, Streptococcus viridans, Escherichia coli, Klebsiella pneumoniae, Enterococcus faecalis, Enterococcus faecium, Enterobacter cloacae, Citrobacter freundii, Proteus mirabilis, Citrobacter diversus, Salmonella spp., penicillin G-susceptible staphylococci, and Enterobacter aerogenes.

Susceptible Gram-negative bacteria should be kept in mind during therapy. In such cases, discontinue the drug instead of changing to another antibacterial agent.

The MIC values obtained should be interpreted according to the criteria provided in “Susceptibility Test Methods.”

Disk Diffusion Method

The disk diffusion method of antimicrobial susceptibility testing of bacteria should be performed using a disc impregnated with Ampicillin (10 mcg). The organism to be tested should be grown on sheep blood agar plates, and suspension of the turbidity equivalent to a 0.5 McFarland standard should be made. Susceptibility test results should be interpreted according to the criteria provided in “Susceptibility Test Result Interpretive Criteria.”

Concentration Sensitivity Testing

The concentration sensitivity testing includes the following serial dilutions of ampicillin: 25, 50, 75, 100, 125, 150, 200, 250, and 500 mcg/mL. The plates are incubated at 35° C for 18 to 24 hours. The lowest concentration not inhibiting the growth of the organism is recorded as the MIC.

CLINICAL PHARMACOLOGY

Absorption

Ampicillin for Injection, USP is rapidly absorbed following IM or IV administration. The mean peak serum concentration occurs at 0.5 hours, the mean terminal elimination half-life is 30 minutes, and the mean area under the serum concentration-time curve is 1,000 mcg-hour/mL. The drug is minimally bound to plasma proteins, averaging about 20% compared to plasma albumin.

Distribution

The least serum-bound of all the penicillins, Ampicillin for Injection, USP is distributed throughout the body, with concentrations typically equal to or slightly greater than serum levels. The distribution half-life of Ampicillin for Injection, USP is 30 minutes, and the volume of distribution is 0.25 L/kg.

Metabolism

Ampicillin for Injection, USP is primarily metabolized in the liver, with less than 2% of the parent compound excreted unchanged in the urine. The urine concentration of Ampicillin for Injection, USP is variable, but concentrations of 800 mcg/mL have been observed. The pH range of the reconstituted solution is 8.0 to 10.0. Ampicillin for Injection, USP is not dialyzable and is not appreciably removed during hemo or hemoperfusion.

Excretion

The renal excretion of Ampicillin for Injection, USP is rapid, accounting for approximately 60 to 90% for other penicillins. Ampicillin for Injection, USP is the least serum-bound of all the penicillins, averaging about 20% compared to plasma albumin.

Renal function, including renal, hepatic and hematopoietic, should be made to provide benefit to the patient and increases the risk of the development of allergy to Ampicillin for Injection, USP should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

Escherichia coli

Listeria monocytogenes, N. meningitidis

Susceptible Gram-negative bacilli should be kept in mind during therapy. In such cases, discontinue the drug instead of changing to another antibacterial agent.

Drug Interactions

Transient elevation of serum transaminase has been observed following Ampicillin for Injection, USP. Administration of Ampicillin for Injection, USP should be discontinued if a marked elevation of serum transaminase occurs. Ampicillin for Injection, USP may be used during the first trimester of pregnancy.

The molecular formula is C16H19N3O6S

REFERENCES

1. Ampicillin for Injection, USP $®
2. Neisseria meningitidis $®
3. Streptococcus pneumoniae $®
4. Haemophilus influenzae $®
5. Escherichia coli $®
6. Proteus mirabilis $®
7. Neisseria gonorrhoeae $®
8. Staphylococcus aureus $®
9. Staphylococcus saprophyticus $®
10. Streptococcus pyogenes $®
11. Streptococcus faecalis $®
12. Streptococcus agalactiae $®
13. Streptococcus viridans $®
14. Enterococcus faecalis $®
15. Enterococcus faecium $®
17. E. coli
18. K. pneumoniae
19. C. freundii
20. E. aerogenes
21. S. aureus
22. S. saprophyticus
23. S. pyogenes
24. S. faecalis
25. S. agalactiae
26. S. viridans
27. Enterococcus faecalis
28. Enterococcus faecium
29. Salmonella spp.
30. E. coli
31. K. pneumoniae
32. C. freundii
33. E. aerogenes
34. S. aureus
35. S. saprophyticus
36. S. pyogenes
37. S. faecalis
38. S. agalactiae
39. S. viridans
40. Enterococcus faecalis
41. Enterococcus faecium
42. Salmonella spp.
43. E. coli
44. K. pneumoniae
45. C. freundii
46. E. aerogenes
47. S. aureus
48. S. saprophyticus
49. S. pyogenes
50. S. faecalis
51. S. agalactiae
52. S. viridans
53. Enterococcus faecalis
54. Enterococcus faecium
55. Salmonella spp.
Ampicillin for Injection, USP

For Intramuscular or Intravenous Use

For Administration by Intravenous Drip:

Diluent: Sterile Water for Injection, USP or Bacteriostatic Water for Injection, USP

Dilution: Sterile Water for Injection, USP or Bacteriostatic Water for Injection, USP, listed in the table below:

Table

<table>
<thead>
<tr>
<th>Volume</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mL</td>
<td>up to 2 mg/mL</td>
</tr>
<tr>
<td>15 mL</td>
<td>10 to 20 mg/mL</td>
</tr>
<tr>
<td>20 mL</td>
<td>500 mg</td>
</tr>
</tbody>
</table>

Concentrations should fall within the diluent and volume are specified on the label of each package.

Dosage:

To help prevent the occurrence of acute rheumatic fever or acute glomerulonephritis.

Bacterial eradication has been obtained. A minimum of 10-days treatment is required.

Central Nervous System:

Seizures.

Intramuscular or intravenous route. A change to oral ampicillin may be made when the product will be used in newborns.

Syphilis is suspected, monthly serological tests should be made for a minimum of 1 year after therapy.

Cases of gonorrhea with a suspected primary lesion of syphilis should have darkfield examination before receiving treatment. In all other cases where concomitant infection is possible, treatment must be given for both infections.

Follow-up for several months after cessation of therapy.


Urticaria, other skin rashes, and serum sickness-like reactions may occur.

A moderate rise in serum glutamic oxaloacetic transaminase (SGOT) has been reported.

Glossitis, stomatitis, black "hairy" tongue, nausea, vomiting, and diarrhea have also been reported.

Skin rashes and urticaria have been reported, particularly in infants, but the significance of this finding is unknown. Mild transitory SGOT elevations have been observed in individuals who have received ampicillin. In some cases these changes are associated with clinical deterioration in patients with hepatic dysfunction.

Whenever such reactions occur, ampicillin should be discontinued, unless, in the opinion of the physician, its continued administration is considered essential. In such cases appropriate supportive measures as required. In patients with renal function impairment, ampicillin-class antibacterials can be removed by hemodialysis but not peritoneal dialysis.

Intramuscular injections may not be as effective as oral therapy because of poor absorption and release at the site of injection.

Penicillin purpura, eosinophilia, leukopenia, and agranulocytosis have been reported, usually in individuals who have previously demonstrated hypersensitivity to penicillins but not to ampicillin. Hypersensitivity phenomena may occur with some frequency.

In patients with a history of allergy, asthma, hay fever, or urticaria, oral ampicillin-class antibacterials are poorly absorbed and may produce immediate or delayed adverse effects on the fetus, prolongs the duration of labor, and may cause the newborn to have a low birth weight and respiratory depression.

In animal studies has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, and may cause the newborn to have a low birth weight and respiratory depression.

In animal studies have been conducted with this drug.

While Ampicillin for Injection, USP 1 g and 2 g, are primarily for intravenous administration, USP is not to be used as a diluent for other intravenous solutions. Therefore, it is recommended that glucose tests (5% Dextrose Injection, USP or Fehling's Solution) are used. Therefore, it is recommended that glucose tests be performed prior to diluting with Intravenous Solution. Stability is a registered trademark of Bayer Corporation.