Ampicillin Sodium

Introduction: Ampicillin is a semi-synthetic derivative of penicillin, active as a broad-spectrum antibiotic.

Mechanism of action: Inhibits bacterial cell wall synthesis by binding to one or more of the penicillin binding proteins (PBPs); which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

Pharmacology:
Absorption: Oral: 50%
Distribution: Bile, blister, and tissue fluids; penetration into CSF occurs with inflamed meninges only, good only with inflammation (exceeds usual MICs)
Protein binding: 15% to 25%
Excretion: Urine (~90% as unchanged drug) within 24 hours.
Indications: Treatment of infections of skin and skin structure, intra-abdominal and gynecologic infections caused by susceptible microorganisms, and mixed infections caused by ampicillin-susceptible organisms and beta-lactamase–producing organisms.

Dosage:
Infants and Children: Mild-to-moderate infections: I.M., I.V.: 100-150 mg/kg/day in divided doses every 6 hours (maximum: 2-4 g/day).
Oral: 50-100 mg/kg/day in doses divided every 6 hours (maximum: 2-4 g/day).
Severe infections/meningitis: I.M., I.V.: 200-400 mg/kg/day in divided doses every 6 hours (maximum: 6-12 g/day).
Endocarditis prophylaxis: I.M., I.V.: Dental, oral, respiratory tract, or esophageal procedures: 50 mg/kg within 30 minutes prior to procedure in patients unable to take oral amoxicillin.
Genitourinary and gastrointestinal tract (except esophageal) procedures: High-risk patients: 50 mg/kg (maximum: 2 g) within 30 minutes prior to procedure, followed by ampicillin 25 mg/kg (or amoxicillin 25 mg/kg orally) 6 hours later; must be used in combination with gentamicin.
Moderate-risk patients: 50 mg/kg within 30 minutes prior to procedure.
Adults: Susceptible infections*:* Oral: 250-500 mg every 6 hours *I.M.*, I.V.: 250-500 mg every 6 hours.
Sepsis/meningitis: I.M., I.V.: 150-250 mg/kg/24 hours divided every 3-4 hours (range: 6-12 g/day).
Endocarditis prophylaxis: I.M., I.V.: Dental, oral, respiratory tract, or esophageal procedures: 2 g within 30 minutes prior to procedure in patients unable to take oral amoxicillin.
Genitourinary and gastrointestinal tract (except esophageal) procedures: High-risk patients: 2 g within 30 minutes prior to procedure, followed by ampicillin 1 g (or amoxicillin 1 g orally) 6 hours later; must be used in combination with Gentamicin.
Moderate-risk patients: 2 g within 30 minutes prior to procedure

Side effects: Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Call your doctor at once if you have any of these serious side effects:

- fever, sore throat, and headache with a severe blistering, peeling, and red skin rash;
- diarrhea that is watery or bloody;
- fever, chills, body aches, flu symptoms;
- easy bruising or bleeding, unusual weakness;
- urinating less than usual or not at all;
- agitation, confusion, unusual thoughts or behavior; or
- Seizure (black-out or convulsions).

Less serious side effects may include

- nausea, vomiting, stomach pain;
- vaginal itching or discharge;
- headache;
- swollen, black, or "hairy" tongue; or
- Thrush (white patches or inside your mouth or throat).

Precautions: Dosage adjustment may be necessary in patients with renal impairment; a low incidence of cross-allergy with other beta-lactams exists; high percentage of patients with infectious mononucleosis have developed rash during therapy with ampicillin. Appearance of a rash should be carefully evaluated to differentiate a nonallergic ampicillin rash from a hypersensitivity reaction. Ampicillin rash occurs in 5% to 10% of children receiving ampicillin and is a generalized dull red, maculopapular rash, generally appearing 3-14 days after the start of therapy. It normally begins on the trunk and spreads over most of the body. It may be most intense at pressure areas, elbows, and knees.

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.

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.

The safety and effectiveness of ampicillin have been established for pediatric patients one year of age and older for skin and skin structure infections as approved in adults. Use of ampicillin in pediatric patients is supported by evidence from adequate and well-controlled studies in adults with additional data from pediatric pharmacokinetic studies, a controlled clinical trial conducted in pediatric patients and post-marketing adverse events surveillance.

Contraindications: Hypersensitivity to ampicillin, any component of the formulation, or other penicillins

How supplied: Customized as per request.