PRESCRIBING INFORMATION
Including Patient Medication Information

APO-AMPI

Ampicillin Trihydrate, USP
250 and 500 mg Capsules

125 mg per 5 mL
250 mg per 5 mL
Powder for Oral Suspension

Antibiotic

Apotex INC.
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Toronto, Ontario
M9L1T9

Control No: 217173

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Pharmacology: Ampicillin, a semisynthetic penicillin, is similar to benzylpenicillin in its bactericidal action against sensitive organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptide.

Ampicillin differs in vitro spectrum from benzylpenicillin in the gram-negative spectrum. It exerts high in vitro activity against many strains of H. influenzae, N. gonorrhoeae, N. meningitidis, B. catarrhalis, E. coli, P. mirabilis, B. funduliformis, Salmonellae and Shigellae.

In vitro studies have also demonstrated the sensitivity of many strains of the following gram positive bacteria: alpha-and beta-hemolytic streptococci, S. pneumoniae, non-beta-lactamase (penicillinase)-producing staphylococci, B. anthracis, and most strains of enterococci and clostridia. Ampicillin generally provides less in vitro activity than penicillin G against gram positive bacteria. Because it does not resist destruction by beta-lactamase, it is not effective against beta-lactamase-producing bacteria, particularly resistant staphylococci. All strains of Pseudomonas and most strains of Klebsiella and Aerobacter are resistant. Ampicillin is not active against Rickettsia, Mycoplasma and 'large viruses' (Chiamydia). Ampicillin is acid stable and therefore, well absorbed. Food, however, retards absorption. Ampicillin diffuses readily into most body tissues and fluids; however, penetration into the cerebrospinal fluid and brain occurs only with meningeal inflammation. Ampicillin is excreted largely unchanged in the urine; its excretion can be delayed by concurrent administration of probenecid. In blood serum, ampicillin is the least bound of all the penicillins; an average of about 20% of the drug is bound to the plasma proteins as compared to 60 to 90% for other penicillins.

The administration of a 500 mg dose of ampicillin trihydrate capsules results in an average peak serum concentration of approximately 3.0 ug/mL.

Indications: 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 producing staphylococci).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of APO-AMPI and other antibacterial drugs, APO-AMPI 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 reaction to penicillin or cephalosporins.

Precautions: 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 myoclonia, convulsive seizures and depressed consciousness can be expected. Although this complication has not been reported with ampicillin, it should be anticipated.

Safety for use during pregnancy has not been established.

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

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing APO-AMPI in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Adverse Effects:

Gastrointestinal: glossitis, stomatitis, black 'hairy' tongue, nausea, vomiting, diarrhea, enterocolitis and pseudomembranous colitis.

Hypersensitivity: Erythematous maculopapular rashes have been reported fairly frequently; urticaria, erythema multi-form, and a few cases of exfoliative dermatitis have been reported. Anaphylaxis is the most serious reaction experienced and has usually been associated with parenteral administration.

Note: 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 i.v. corticosteroids. In some cases of infectious mononucleosis, where ampicillin has been administered, an extremely high incidence of generalized rash has been reported.

Hematologic: Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia ana agranulocytosis have been reported. These are usually reversible on discontinuation of the drug, and are believed to be hypersensitivity phenomena.

Dosage Oral: Oral doses are preferably given 1 hour before meals, and therapy maintained for u minimum of 5 days. Adults, and children over 20 kg-E.N.T. and respiratory tract infections: 250 mg every 6 hours. Genitourinary and gastrointestinal tract infections: 500 mg every 6 to 8 hours. For more severe infections, these doses should be increased or doubled. Children under 20 kg-respiratory, genitourinary, and gastrointestinal tract infections:

Body Weight of Child	**Total Daily Dosage-Oral**
Up to 5 kg (approx. 3 months)	250 to 500 mg
Over 5 kg upto 20 kg	25 to 100 mg/kg

This total dosage must be divided into equal doses, and each dose administered every 6 hours.

Larger doses may be required for stubborn or severe infections. The children's dosages are intended for individuals whose weights will not result in a 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.

Continue treatment for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication can been obtained. A minimum of 10 days' treatment is recommended for any infection caused by beta-hemolytic streptococci.

In gonorrhea therapy, perform serologic tests for syphilis initially and monthly for 3 months.

Dosage Forms:
Capsules: Each scarlet and black #2 capsule, imprinted APO 250 contains Ampicillin Trihydrate equivalent to 250 mg of Ampicillin. Supplied in bottles of 100 and 1000 capsules.

Each scarlet and black #0 capsule imprinted APO 500 contains Ampicillin Trihydrate equivalent to 500 mg of Ampicillin. Supplied in bottles of 100 and 1000 capsules.

Powder for Oral Suspension: After reconstitution of the cherry flavoured powder, each 5 mL contains Ampicillin Trihydrate equivalent to 125 mg (or 25 mg per mL) or 250 mg (or 50 mg per mL) of Ampicillin.

Instructions for reconstitution:

At the time of dispensing SHAKE BOTTLE TO LOOSEN POWDER. To reconstitute, add the following quantities of water:

	Strengths	
Pack Size	125 mg/5 mL	250 mg/5 mL
60 mL	42mL	42mL
100 mL	70 mL	70 mL
150 mL	105 mL	105 mL

Shake thoroughly to obtain a uniform suspension.

The reconstituted suspension is stable for 21 days when refrigerated at 40°F (4.5°C). Do not freeze.