Ampecin Leaflet
Size: A5
148 x 210mm

Ampecin

Ampicillin BP 125mg / 5ml

Description:
Ampicillin is a beta-lactam antibiotic and has a bactericidal action against Gram-positive bacteria, Gram-negative cocci, some other Gram-negative bacteria, spirochaetes, and actinomycetes.

Composition:
Each 5 ml of the reconstituted suspension contains Ampicillin (as trihydrate) 125 mg; excipients: Strawberry flavor, Sodium benzoate, Ponceau 4R colour, Sodium citrate, Sodium CMC, Sodium chloride & Sucrose.

Pharmacology:
Ampicillin exerts its bactericidal action on growing and dividing bacteria by inhibiting bacterial cell-wall synthesis. Bacterial cell walls are held rigid and protected against osmotic rupture by peptidoglycan. Ampicillin inhibits the final cross-linking stage of peptidoglycan production by binding to and inactivating transpeptidases, penicillin-binding proteins on the inner surface of the bacterial cell membrane. However, it is now realised that other earlier stages in cell-wall synthesis can also be inhibited. Other mechanisms involved include bacterial lysis by the inactivation of endogenous inhibitors of bacterial autolysins. Its action is inhibited by penicillinase and other beta-lactamases that are produced during the growth of certain micro-organisms.
As an aminopenicillin with an amino group side-chain attached to the basic penicillin structure, ampicillin is better able to penetrate the outer membrane of some Gram-negative bacteria and has a broader spectrum of activity than benzyl penicillin.
Spectrum of activity:
Ampicillin acts against Gram-positive organisms, including Streptococcus pneumoniae and other streptococci, Listeria monocytogenes is highly sensitive. The Gram-negative cocci Moraxella catarrhalis (Branhamella catarrhalis), Neisseria gonorrhoeae, and N. meningitidis are sensitive. Ampicillin is active against some Gram-negative bacilli, including Haemophilus influenzae and Enterobacteriaceae such as Escherichia coli, Proteus mirabilis, Salmonella and Shigella spp, and rifampicin.

Pharmacokinetics:
Ampicillin is relatively resistant to inactivation by gastric acid and is moderately well absorbed from the gastrointestinal tract after oral doses. Food can interfere with the absorption of ampicillin so doses should preferably be taken at least 30 minutes before meals. Peak concentrations in plasma are attained in about 1 to 2 hours and after a 500-mg oral dose are reported to range from 3 to 6 micrograms/mL. Ampicillin is widely distributed and therapeutic concentrations can be achieved in ascitic, pleural, and joint fluids. It crosses the placenta and small amounts are distributed into breast milk. There is little diffusion into the CSF except when the meninges are inflamed. About 20% is bound to plasma proteins and the plasma half-life is about 1 to 1.5 hours, but this may be increased in neonates, the elderly, and patients with renal impairment; in severe renal impairment half-lives of 7 to 20 hours have been reported. Ampicillin is metabolised to some extent to penicilloic acid which is excreted in the urine. Renal clearance of ampicillin occurs partly by glomerular filtration and partly by tubular secretion; it is reduced by probenecid. About 20 to 40% of an oral dose may be excreted unchanged in the urine in 6 hours; urinary concentrations have ranged from 0.25 to 1 mg/mL following a dose of 500 mg.

Indications:
Ampicillin is used in the treatment of a variety of infections due to susceptible organisms. They include biliary-tract infections, bronchitis, endocarditis, gastro-enteritis (including salmonella enteritis and shigellosis), gonorrhoea, listeriosis, meningitis, perinatal streptococcal infections (intrapartum prophylaxis against group B streptococci), peritonitis, pneumonia, septicaemia, typhoid and paratyphoid fever, and urinary-tract infections. Resistance to ampicillin is increasingly a problem in some infections, for example, gonorrhoea, pneumococcal infections, respiratory-tract infections due to Haemophilus influenzae or Moraxella catarrhalis (Branhamella catarrhalis), Salmonella infections, shigellosis, and infections due to Escherichia coli. If beta-lactamase-producing organisms are present, ampicillin can be given with a beta-lactamase inhibitor such as sulbactam or a penicillinase-resistant drug such as cloxacillin, dicloxacillin, or flucloxacillin. It may also be used with an aminoglycoside to increase the spectrum of organisms covered; it is advisable to administer the injections separately.

Contraindications and precautions:
Patients known to be hypersensitive to penicillins should be given an antibacterial of another class. Penicillins should be given with caution to patients with a history of allergy, especially to drugs. Care is necessary if very high doses of penicillins are given, especially if renal function is poor, because of the risk of neurotoxicity. The intrathecal route should be avoided. Renal, hepatic, and haematological status should be monitored during prolonged and high-dose therapy. Because of the Jarisch-Herxheimer reaction, care is also necessary when treating patients with spirochaete infections, particularly syphilis. Skin contact with penicillins should be avoided since sensitisation may occur.
Ampicillin therapy changes the normal bacterial flora and can lead to supra-infection with penicillin-resistant organisms including Clostridium difficile or Candida, particularly with prolonged use. Ampicillin may interfere with some diagnostic tests such as those for urinary glucose using copper sulfate, direct antiglobulin (Coombs') tests, and some tests for urinary or serum proteins. Ampicillin may interfere with tests that use bacteria, for example the Guthrie test for phenylketonuria using Bacillus subtilis organisms.

Adverse reactions:
Skin rashes are among the most common adverse effects and are generally either urticarial or maculopapular; the urticarial reactions are typical of penicillin hypersensitivity, while the erythematous maculopapular eruptions are characteristic of ampicillin and amoxicillin and often appear more than 7 days after commencing treatment. Such rashes may be due to hypersensitivity to the beta-lactam moiety or to the amino group in the side-chain, or to a toxic reaction. The occurrence of a maculopapular rash during ampicillin use does not necessarily preclude the subsequent use of other penicillins. However, since it may be difficult in practice to distinguish between hypersensitive and toxic responses, skin testing for hypersensitivity may be advisable before penicillin is used in patients who have had ampicillin rashes. Most patients with infectious mononucleosis develop a maculopapular rash when treated with ampicillin, and patients with other lymphoid disorders such as lymphatic leukemia and possibly HIV infection also appear to be at higher risk. More serious skin reactions may occur and erythema multiforme associated with ampicillin has occasionally been reported. Gastrointestinal adverse effects, particularly diarrhoea and nausea and vomiting, occur quite frequently, usually after oral use. Pseudomembranous colitis has also been reported.

Dosage and directions for use:
The dosage of ampicillin will depend on the severity of the disease, the age of the patient, and renal function. Ampicillin is usually given by mouth as the trihydrate and by injection as the sodium salt. The usual adult dose by mouth is 0.25 to 1 g every 6 hours taken at least 30 minutes before or 2 hours after food. Children may be given half the adult dose. The usual adult dose by injection is 500 mg every 4 to 6 hours intramuscularly or by slow intravenous injection over 3 to 5 minutes or by infusion. Again, children may be given half the adult dose. For urinary-tract infections, ampicillin 500 mg is given by mouth every 8 hours.
For typhoid and paratyphoid fever where Salmonella typhi strains remain sensitive to ampicillin, an oral dose of 1 to 2 g may be given every 6 hours for 2 weeks for acute infections, and for 4 to 12 weeks in carriers. An intramuscular dose of 10 mg/kg (maximum dose 250 mg) every 6 hours for 4 to 6 weeks has been suggested for children who are chronic carriers.
In meningitis, higher parenteral doses of 2 to 3 g given intravenously every 4 or 6 hours have been suggested. For infants and children with meningitis, an intravenous dose of 150 mg/kg daily in divided doses may be given; a dose of 50 mg/kg (maximum 3 g) every 4 to 6 hours has also been suggested. Neonates may be given a dose of 50 mg/kg every 12 hours for those under 1 week of age, or every 8 hours for older neonates.
For intrapartum prophylaxis against group B streptococcal infection in the neonate, a maternal dose of 2 g by intravenous injection initially then 1 g every 4 hours until delivery has been suggested.Ampicillin may also be administered by other routes, usually as a supplement to systemic therapy. Intraperitoneal or intrapleural injections are given in a dose of 500 mg daily dissolved in 5 to 10 mL of water. For intra-articular injection, ampicillin 500 mg daily is given dissolved in up to 5 mL of water or a solution of procaine hydrochloride 0.5%.

Distribution Category: POM

Presentation
Dry powder for oral suspension: Bottles containing dry powder for reconstitution of 60 and 100 ml of suspension.

Storage: Do not store above 30°C. Protect from direct sunlight. Keep all medicines out of reach of children.
Dry powder for suspension: Once reconstituted, store under refrigerator and use within 7 days.

Manufactured by:

Dawa Limited
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