℞ *For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.*

Ampicillin & Sulbactam for Injection

AMERICAN
AMPIGYL SB
Injection

1.5 gm

For IM / IV Use Only.

Composition :

Each vial contains :

Ampicillin Sodium IP (Sterile) eq. to Anhydrous Ampicillin	1.0 g
Sulbactam Sodium IP (Sterile) eq. to Anhydrous Sulbactam	0.5 g

MECHANISM OF ACTION

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 muco-peptide biosynthesis during the stage of active multiplication. Sulbactam, a penicillanic acid sulfone with β-lactamase inhibitory properties has weak antibacterial activity, but is an irreversible inhibitor of many plasmid-mediated and some chromosomal β-lactamases. It has a similar spectrum of β-lactamase inhibition to clavulanic acid. It enhances the activity of penicillins and cephalosporins.

PHARMACOKINETICS

Ampicillin diffuses readily into most body tissues and fluids. However, penetration into the cerebrospinal fluid and brain occurs only when the meninges are inflamed. Ampicillin is excreted largely unchanged in the urine and its excretion can be delayed by concurrent administration of probenecid. The active form appears in the bile in higher concentrations than those found in serum. Ampicillin is the least serum-bound of all the penicillins, averaging about 20% compared to approximately 60 to 90% for other penicillins. Ampicillin is excreted mainly in the bile and urine with a plasma half life of 1 – 2 hours. Sulbactam is poorly absorbed from the GI tract. It is distributed into breast milk. Protein binding is 38%. Half-life elimination is 1-1.3 hr. About 75-85% is excreted unchanged in the urine within 8 hr.

INDICATIONS

- Skin and Skin Structure Infections
- Intra-Abdominal Infections
- Gynecological Infections
- Respiratory tract Infections
- Bacterial Meningitis Septicemia and Endocarditis
- Urinary Tract Infections

DOSAGE

Ampigyl SB may be administered by either the IV or the IM routes.

For IV administration, the dose can be given by slow intravenous injection over at least 10–15 minutes or can also be delivered, in greater dilutions with 50–100 mL of a compatible diluent as an intravenous infusion over 15–30 minutes.

For IM administration the dose can be given by deep intramuscular injection.

The recommended adult dosage is 1.5 g (1 g ampicillin as the sodium salt and 0.5 g sulbactam as the sodium salt) to 3 g (2 g ampicillin as the sodium salt and 1 g sulbactam as the sodium salt) every six hours.

Pediatric Patients 1 Year of Age or Older: The recommended daily dose in pediatric patients is 300 mg per kg of body weight administered via intravenous infusion in equally divided doses every 6 hours. Pediatric patients weighing 40 kg or more should be dosed according to adult recommendations, and the total dose of sulbactam should not exceed 4 grams per day. The course of intravenous therapy should not routinely exceed 14 days.

Preparation of Injection

For intramuscular administration

Ampigyl SB is dissolved in sterile water for injections or in 0.5 -1% solution of lidocaine hydro-chloride. Sensitivity test to lidocaine is obligatory prior to the intramuscular injection. 1.6 ml of solvent are added to the contents of the vials of 0.75 g; 3.2 ml to the vials of 1.5 g and 6.4 ml to the vials of 3 g. The resultant solution can be used within 1 hr. To be injected only deeply intramuscularly.

For intravenous administration

Ampigyl SB is dissolved in water for injections, saline, or 5% glucose. Await to be obtained a clear solution without bubbles. To the contents of the vials of 0.75 g are added 25 ml of solvent, to the contents of the vials of 1.5 g - 50 ml and to the contents of the vials of 3.0 g - 100 ml. The dose of the antibiotic can be given by slow intravenous injection, over at least 4 min or after complementary dilution, slowly infused over 15-30 ml.

CONTRAINDICATIONS

Ampicillin is a penicillin and should not be given to patients with a history of hyper-sensitivity to beta-lactam antibiotics (e.g. ampicillin, penicillins, cephalo-sporins) or excipients. Sulbactam is contraindicated in hypersensitivity reactions.

WARNINGS & PRECAUTIONS

Before initiating therapy with ampicillin, careful enquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics. Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of beta-lactam hypersensitivity. Ampicillin should be avoided if infectious mononucleosis and/or acute or chronic leukaemia of lymphoid origin are suspected. The occurrence of a skin rash has been associated with these conditions following the administration of ampicillin. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. Dosage should be adjusted in patients with renal impairment. Sulbactam should be taken with precaution in hepatic disease, biliary obstruction, ingestion of alcohol, pregnancy and lactation.

DRUG INTERACTIONS

If Ampicillin is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions. Bacteriostatic drugs may interfere with the bactericidal action of ampicillin. In common with other oral broad-spectrum antibiotics, ampicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly. Probenecid decreases the renal tubular secretion of ampicillin. Concurrent use with ampicillin may result in increased and prolonged blood levels of ampicillin. Concurrent administration of allopurinol during treatment with ampicillin can increase the likelihood of allergic skin reactions. It is recommended that when testing for the presence of glucose in urine during ampicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of ampicillin, false positive readings are common with chemical methods. Probenecid may increase the serum concentrations of sulbactam.

PREGNANCY&LACTATION

Pregnancy: Animal studies with Ampicillin have shown no teratogenic effects. The product has been in extensive clinical use since 1961 and its use in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, Ampicillin may be considered appropriate.

Lactation: During lactation, trace quantities of penicillins can be detected in breast milk. Adequate human and animal data on use of Ampicillin during lactation are not available.

SIDE EFFECTS

Hypersensitivity reactions: If any hypersensitivity reaction occurs, the treatment should be discontinued. Skin rash, pruritus and urticaria have been reported occasionally. The incidence is higher in patients suffering from infectious mononucleosis and acute or chronic leukaemia of lymphoid origin. Purpura has also been reported. Rarely, skin reactions such as erythema multiforme, Stevens Johnson syndrome and toxic epidermal necrolysis have been reported. As with other antibiotics, anaphylaxis has been reported rarely.

Renal effects: Interstitial nephritis can occur rarely.

Gastrointestinal reactions: Effects include nausea, vomiting and diarrhoea. Pseudomembraneous colitis and haemorrhagic colitis has been reported rarely.

Hepatic effects: As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely. As with most other antibiotics, a moderate and transient increase in transaminases has been reported.

Haematological effects: As with other beta-lactams, haematological effects including transient leucopenia, transient thrombocytopenia and haemolytic anaemia have been reported rarely. Prolongation of bleeding time and prothrombin have also been reported rarely.

Sulbactum side effects include GI disturbances; hypersensitivity reactions.

And potentially Fatal Stevens-Johnson syndrome.

OVERDOSAGE

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically. Ampicillin may be removed from circulation by haemodialysis.

Storage :Store below 30°C. Protect from light & moisture. Do not freeze.
Improper storage may deteriorate the product.

Medicine: Keep out of reach of children.

PRESENTATION :

Available as **AMPIGLY SB** Injection 1.5 gm vial.

Manufactured by:
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Care & Cure with Research
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