

# SPEYBACT

## Instructions for the medicinal product

### Composition:

*Speybact 0.75 g:* Each vial contains:

Ampicillin Sodium USP (Sterile) eq. to Anhydrous Ampicillin 0.5 g  
Sulbactam Sodium USP (Sterile) eq. to Sulbactam 0.25 g

*Speybact 1.5 g:* each vial contains:

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

**ATC Code:** J01CR01.

*Speybact 0.75 g:*

### Product Description:

*Physical properties:* White colour Crystalline powder, 0.75 g in 15 ml Clear Glass Vial.

*Chemical name:* Ampicillin Sodium & Sulbactam Sodium.

*Molecular weight:* 371.386589 g/mol & 255.223469 g/mol.

*Empirical / Structural formula:* C<sub>16</sub>H<sub>18</sub>N<sub>3</sub>NaO<sub>4</sub>S & C<sub>8</sub>H<sub>10</sub>NNaO<sub>5</sub>S.

*Speybact 1.5 g:*

### Product Description:

*Physical properties:* White colour Crystalline powder, 1.5 g in 20 ml Clear Glass Vial.

*Chemical name:* Ampicillin Sodium & Sulbactam Sodium.

*Molecular weight:* 371.386589 g/mol & 255.223469 g/mol.

*Empirical / Structural formula:* C<sub>16</sub>H<sub>18</sub>N<sub>3</sub>NaO<sub>4</sub>S & C<sub>8</sub>H<sub>10</sub>NNaO<sub>5</sub>S.

### Pharmacodynamics:

Ampicillin and sulbactam is a combination of the common penicillin-derived antibiotic ampicillin and sulbactam, an inhibitor of bacterial beta-lactamase. There are two forms of this drug. Ampicillin and sulbactam is used to treat infections caused by bacteria resistant to beta-lactam antibiotics. Sulbactam blocks the enzyme which breaks down ampicillin and thereby allows ampicillin to attack and kill the bacteria.

Ampicillin exerts bactericidal action on both gram-positive and gram-negative organisms. Its spectrum includes *gram-positive organisms* e.g. S pneumoniae and other Streptococci, L monocytogenes and *gram-negative bacteria* e.g. M catarrhalis, N gonorrhoea, N meningitidis, E coli, P mirabilis, Salmonella, Shigella, and H influenzae. Ampicillin exerts its action by inhibiting the synthesis of bacterial cell wall. Sulbactam inhibits β-lactamases and extends the spectrum of ampicillin to include β-lactamase producing pathogens.

### Pharmacokinetics:

*Distribution:* Into bile, blister and tissue fluids; poor penetration into CSF with uninflamed meninges; higher concentrations attained with inflamed meninges

*Protein binding:* Ampicillin: 28%; Sulbactam: 38%

*Half-life:* Ampicillin and sulbactam are similar: 1-1.8 hours and 1-1.3 hours, respectively in patients with normal renal function

*Elimination:* ~75% to 85% of both drugs are excreted unchanged in the urine within 8 hours following administration.

### Indication:

Bacterial infections of different localization caused by susceptible pathogens:

- Respiratory infections (including pneumonia, lung abscess, chronic bronchitis, empyema);
- Upper respiratory tract infections (including sinusitis, tonsillitis, otitis media);
- Infections of the urinary tract and genital organs (pyelonephritis, pyelitis, cystitis, urethritis, prostatitis, endometritis);
- Biliary tract infections (cholecystitis, cholangitis);
- Infections of skin and soft tissue (face, impetigo, secondarily infected dermatitis);
- Gastrointestinal infections (dysentery, salmonellosis, Salmonella carriage);
- Bone and joint infections;
- Bacterial endocarditis, meningitis, sepsis, peritonitis, scarlet fever, gonococcal infection;
- Prevention of postoperative complications in surgery of the abdomen and pelvis.

### Recommended Dose and Mode of Administration:

Speybact may be administered by either the IV or the IM routes (drip at a rate of 60-80 drops/min, jet - slowly during 3-5 min). IV administered 5-7 days, and then, if necessary further treatment, should to use IM route.

Further are the total doses of ampicillin and sulbactam ( is 2:1).

*Mild infection* - 1.5-3 g / day in 2 administration; with moderate flow 3-6 g/day in 3-4 introduction; in severe - 12 g/day in 3-4 administration.

*Uncomplicated gonorrhoea* - 1.5 g, once.

*Prevention of surgical site infections* - 1.5-3 g during anesthesia, and then for 24 hours after the operation - at the same dose every 6-8 hours. Children - a daily dose rate is 150 mg/kg (of 100 mg/kg ampicillin and 50 mg/kg sulbactam); multiple - 3-4 times per day.

Newborns till 1 week of life and premature babies - every 12 hours.

Duration of treatment 5-14 days (if necessary, may be extended). After normalization of temperature and the disappearance of other pathological symptoms treatment should be continued for a further 48 hours.

With *chronic renal failure (creatinine clearance less than 30 mL / min)* to increase the intervals between injections.

The solution for parenteral administration is prepared ex tempore. To the contents of the vial were added 2 or 4 ml of water for injection 0.5% solution of procaine or 0.9% solution of NaCl. For the IM is acceptable dilution of 0.5% lidocaine. For IV single dose administration is dissolved in 0.9% NaCl solution or 5% dextrose solution in a volume of 10 to 200 ml.

### Contraindications:

- Hypersensitivity to ampicillin, sulbactam or any component, or penicillins;
- Infectious mononucleosis;
- Lactation (breastfeeding).

The solvent containing lidocaine hydrochloride should not be used when increased sensitivity to local anesthetics and severe cardio - vascular diseases.

### Warnings and Precautions:

A high percentage of patients with mononucleosis who receive ampicillin develop a skin rash. Thus, ampicillin class antibiotics should not be administered to patients with mononucleosis. In patients treated with Speybact the possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Pseudomonas or Candida), the drug should be discontinued and/or appropriate therapy instituted. Prescribing Ampicillin and Sulbactam for Injection in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

### Interactions with Other medicaments:

Probenecid decreases the renal tubular secretion of ampicillin and sulbactam. Concurrent use of probenecid with ampicillin and sulbactam for injection may result in increased and prolonged blood levels of ampicillin and sulbactam. The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients. There are no data with ampicillin and sulbactam for injection and allopurinol administered concurrently. Ampicillin and sulbactam for injection and aminoglycosides should not be reconstituted together due to the in vitro inactivation of aminoglycosides by the ampicillin component of ampicillin and sulbactam for injection.

### Pregnancy and Lactation:

During pregnancy, the drug can be annotated only by prescription and under the supervision of a physician. If necessary of using during lactation should decide on the termination of breastfeeding.

### Undesirable Effects:

*Digestive system:* nausea, vomiting, loss of appetite, diarrhea, increased activity of "liver" transaminases, rare - pseudomembranous enterocolitis.

*Hematopoiesis and hemostasis system:* anemia, leukopenia, thrombocytopenia.

*Nervous system:* drowsiness, fatigue, and headache.

*Laboratory parameters:* azotemia, increasing the concentration of urea, hypercreatininemia.

*Allergic reaction:* hives, skin flushing, angioedema, rhinitis, conjunctivitis, fever, arthralgia, eosinophilia, in rare cases - anaphylactic shock.

*Local reactions:* intramuscular administration - pain at the injection site, Intravenous administration - phlebitis.

*Other:* long-term treatment - superinfection caused by drug-resistant microorganisms (Candidiasis).

### Overdose and Treatment:

*Symptoms:* in very high doses of penicillin can cause brain (epileptic) seizures.

*Treatment:* as ampicillin and sulbactam are removed from the circulation by hemodialysis, therefore when they overdose patients with impaired renal function, in order to accelerate the elimination of drugs from the body recommended hemodialysis.

### Dosage Forms and Packaging Available:

*Speybact 0.75 g:* 1x1, 15 ml vial in a monocarton, with instruction for use.

*Speybact 1.5 g:* 1x1, 20 ml vial in a monocarton, with instruction for use.

### Storage:

Keep in dry place protected from light at a temperature below 30°C. Keep out of reach of children.

### Shelf life:

3 years. Do not use after expiry date.

### Distribution Condition:

Prescription only medicine (POM).