1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1 NAME OF THE MEDICINAL PRODUCT

Ampicillin sodium for injection 1g.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

CONSTITUENTS **Each vial contains:**	**Quantity per vial**	**Reason to include**
Amoxicillin Sodium	1.0g	Active

3 PHARMACEUTICAL FORM

Powder for Injection.

White or almost white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Ampicillin is broad-spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin-sensitive organisms. Typical indications include: ear, nose and throat infections, bronchitis, pneumonia, urinary tract infections, gonorrhoea, gynaecological infections, septicaemia, peritonitis, endocarditis, meningitis, enteric fever, gastro-intestinal infections.

Extraperitoneal application of Ampicillin to wounds can be used to prevent infection following abdominal surgery.

Parenteral usage is indicated where oral dosage is inappropriate.

Routes of administration: Intramuscular, intravenous, intraperitoneal, intrapleural, intra-articular, extraperitoneal.

4.2 Posology and method of administration

Usual adult dosage (including elderly patients):

Septicaemia, endocarditis, osteomyelitis: 500 mg four to six times a day IM or IV for one to six weeks.

Peritonitis, intra-abdominal sepsis: 500mg four times a day IM or IV.

Meningitis: Adult dosage: 2 g six-hourly IV.

Children dosage: 150 mg/kg daily IV in divided doses.

Ampicillin may also be administered by other routes of conjunction with systemic therapy.

Intraperitoneal: 500 mg daily in up to 10 ml Water for Injections BP.

Intrapleural: 500 mg daily in 5-10 ml Water for Injections BP.

Intra-articular: 500 mg daily, in up to 5 ml Water for Injections BP or sterile 0.5% procaine hydrochloride solution.

Local use in abdominal surgery: 1 g sterile powder sprinkled into the wound extraperitoneally or into muscle layers to prevent wound infection post operatively.

Usual children's dosage (under 10 years)

Half adult routine dosage.

All recommended dosages are a guide only. In severe infections the above dosages may be increased.

Renal Impairment

In the presence of severe renal impairment (creatinine clearance <10ml/min) a reduction in dose or extension of dose interval should be considered. In cases of dialysis, an additional dose should be administered after the procedure.

Administration:

Intramuscular: Add 1.5 ml Water for Injections BP to 500mg vial contents.

Intravenous: Dissolve 500 mg in 10 ml Water for Injections BP. Administer by slow injection (three to four minutes). Ampicillin may also be added to infusion fluids or injected, suitably diluted, into the drip tube over a period of three to four minutes.

4.3 Contraindications

Ampicillin is penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. ampicillin, penicillins, cephalosporins) or excipients.

4.4 Special warnings and precautions for use

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 (see section 4.2).

Sodium content: One vial contains 33.7 mg of sodium. This sodium content should be included in the daily allowance of patients on sodium restricted diets.

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6 Fertility, pregnancy and 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.

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable 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 and 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.

4.9 Overdose

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: J01CA01,

Ampicillin sodium is a broad-spectrum semi-synthetic penicillins. The product has strong antibacterial effects on hemolytic streptococcus, streptococcus pneumoniae and no-penicillase-producing Staphylococcus, similar to or slightly inferior to penicillin. Ampicillin also had good antibacterial effect on Streptococcus aeruginosa, and its effect on Enterococcus and listeria is better than that of penicillin. This product has antibacterial activity against Corynebacterium diphtheria, Bacillus anthracis, actinomycetes, Haemophilus influenzae, Bauter pertussis, Neisseria and anaerobes except Bacteroides fragilis. Some Proteus mirabilis, Escherichia coli, Salmonella and Shigella are sensitive to this product.

Ampicillin has a bactericidal effect by inhibiting bacterial cell wall synthesis.

5.2 Pharmacokinetic properties

Intramuscular injection of this product 0.5g, blood drug peak concentration (Cmax) arrived at 0.5~1 hour, is 12mg/L, blood concentration at 6h is 0.5mg/L. After intravenous injecting 0.5g the blood concentration at 15min and 4h is 17mg/L and 0.6mg/L. After intramuscular injecting 10mg/kg and 25mg/kg as per body weight to newborns and premature infants, the blood concentration at 1h reaches peak value, is 20mg/L and 60mg/L. The blood concentration of pregnant women was significantly lower than that of non-pregnant women.

The distribution of this product is good in vivo. Patients with bacterial meningitis were injected intravenously with 150mg/kg per day as per body weight, and the concentration in cerebrospinal fluid reached 2.9mg/kg in the first 3 days, and then decreased with the reduction of inflammation. Only a small amount of ampicillin was found in normal cerebrospinal fluid. This product can pass through the placental barrier and reach a certain concentration in amniotic fluid. The concentration of the bronchial secretion in the patients with lung infection was 1/50 of the plasma concentration in the same period. There are considerable amounts of this product in the chest and abdomen water, eye and atrial fluid, articular effusion and milk. The average concentration of typhoid fever in bile was more than 3 times of that in blood, and the highest was 17.8 times. The serum protein binding rate was 20%, the half-life of blood elimination (T1/2 β) was 1~1.5 hours, and the neonatal T1/2 β was 1.7~4 hours. The renal insufficiency patients could be prolonged to 7~20 hours. The ampicillin excreted in urine 24 hours after intramuscular injection and intravenous injection was 50% and 70% of the dosage, respectively, and a small amount of ampicillin was metabolized inactivated in the liver or excreted through bile. This product can be removed by hemodialysis and can’t be removed by peritoneal dialysis.

5.3 Preclinical safety data

N/A

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not applicable.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened 3 years.

6.4 Special precautions for storage

Store below 30°C and protect from light.

Keep out of reach of children.

6.5 Nature and contents of container

Packed in glass vial with rubber stopper, 1g in a vial and 1vial in a box with 1 ampoule of 5ml water for injection.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special instructions for use/handling.

7 MARKETING AUTHORISATION HOLDER

Company Name: KRISHAT PHARMA INDUSTRIES LTD

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