Bosch

For Medical Professional only

Ampin

250mg Injection
500mg Injection

ایمپن انجکشن

(Ampicillin Sodium for Injection U.S.P)

(Product Specs.: U.S.P.)

DESCRIPTION
Ampicillin for injection, USP the monosodium salt of [2S-[2,5,6(S*)]]-6-[(aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, is a synthetic penicillin.

The molecular formula is $C_{16}H_{18}N_3NaO_4S$, and the molecular weight is 371.39. Ampicillin for injection, USP contains 2.86 milliequivalents of sodium per 1 gram of drug.

Ampicillin for injection, USP is white to off-white crystalline powder. The solution after constitution is clear and colorless.
Each vial contains ampicillin sodium equivalent to 250 mg and 500 mg ampicillin per vial. The sodium content is 16.46 mg (0.72 mEq) per 250 mg and 32.91 mg (1.43 mEq) per 500 mg of ampicillin.

PHARMACOLOGICAL PARTICULARS
Mechanism of action
The mechanism of action of ampicillin is based on inhibition of bacterial wall synthesis (in the growth phase) via blockade of the penicillin-binding proteins (PBPs) such as the transpeptidases. This results in a bactericidal action.

Pharmacokinetic properties:
Distribution:
Ampicillin is extensively distributed to tissues, crosses the placental barrier and diffuses into breast milk. Only 5 % of the ampicillin concentration in plasma diffuses into cerebrospinal fluid (CSF) with intact meninges. With inflamed meninges, the ampicillin concentration in CSF can increase to 50 % of the ampicillin concentration in plasma.

The serum protein binding is 17-20 %. The apparent volume of distribution is about 15 L. Higher concentrations of the active form are observed in bile than in serum. After intramuscular injection, peak plasma levels are reached after 30 to 60 min.

Metabolism:
Biotransformation Ampicillin is partly metabolized to microbiologically inactive penicilloates.

Elimination:
Ampicillin is eliminated intact mainly by the renal route, but also through bile and faeces. After oral administration, about 40 % of a dose is recovered unchanged in the urine. After parenteral administration, about 73 +/- 10 % of an administered dose is excreted as unchanged substance in the 0- to 12-hour urine. Up to 10 % of a dose is eliminated in the form of biotransformation products. The elimination half-life is about 50 to 60 min. In oliguria, the half-life may be prolonged to 8 to 20 hours. The half-life is also prolonged in newborns (2 to 4 hours). The renal clearance of ampicillin is about 194 ml/min after intravenous administration.

CLINICAL PARTICULARS:
Therapeutic Indications
Ampicillin is a 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
- Respiratory tract infections
- Urinary tract infections
- Gonorrhoea
- Gynaecological infections
- Septicaemia, peritonitis
- Endocarditis
- Meningitis
- Enteric fever
- Gastrointestinal 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.

DOSAGE AND ADMINISTRATION
Adult dosage
Intravenous or intra-muscular injection
500mg every 4 to 6 hours (the daily dose can be increased to 6 g in case of severe infection)

Paediatric dosage (up to 12 years of age)
Intravenous injection or infusion

Child 1 month – 12 years
25mg/kg (max 1g) every 6 hours (the dose can be doubled in case of severe infection to 50 mg/kg (max 2 g) every 6 hours).
Neonate 21 – 28days
30mg/kg every 6 hours (the dose can be doubled in case of severe infection)
Neonate 7 – 21 days
30mg/kg every 8 hours (the dose can be doubled in case of severe infection)
Neonate under 7 days
30mg/kg every 12 hours (the dose can be doubled in case of severe infection)

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

Special populations
Renal Impairment
No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.
For severely impaired renal function with a glomerular filtration rate of 30 ml/min and less, a reduction in the dose is recommended, since an accumulation of ampicillinis to be expected:
- At a creatinine clearance of 20 to 30 ml/min, the normal dose should be reduced to two-third.
- At a creatinine clearance below 20 ml/min, the normal dose should be reduced to one-third.

As a general rule, a dose of 1 g ampicillin in 8 hours should not be exceeded in patients with severe renal insufficiency

METHOD OF ADMINISTRATION
Use only freshly prepared solutions. Intramuscular and intravenous injections should be administered within one hour after preparation since the potency may decrease significantly after this period.

For Intramuscular Use – Dissolve contents of a vial with the amount of Sterile Water for Injection, USP, or Bacteriostatic Water for Injection, listed in the table below:

Label Claim	Recommended amount of diluent	With drawable. Volume	Concentration (in mg/ml)
250 mg	1 ml	1 ml	250 mg
500 mg	1.8 ml	2 ml	500 mg

For Direct Intravenous Use – Add 5 mL Sterile Water for Injection, USP, or Bacteriostatic Water for Injection, USP to the 250, and 500 mg vials and administer slowly over a 3- to 5- minute period. CAUTION: More rapid administration may result in convulsive seizures.

For Administration by Intravenous Drip – Reconstitute as directed above (For Direct Intravenous Use) prior to diluting with Intravenous Solution. Stability studies on ampicillin sodium at several concentrations in various intravenous solutions indicate the drug will lose less than 10% activitiy at the temperatures noted for the time periods stated.

Room Temperature (25° C)

Diluent	Concentrations	Stability Periods
Sterile Water for Injection	up to 30 mg/mL	8 hours
Isotonic Sodium Chloride	up to 30 mg/mL	8 hours
5% Dextrose in Water	10 to 20 mg/mL	1 hour
5% Dextrose in Water	up to 2 mg/mL	2 hours
5% Dextrose in 0.45% NaCl	up to 2 mg/mL	2 hours
Lactated Ringer's Solution	up to 30 mg/mL	8 hours

Refrigerated (4° C)

Diluent	Concentrations	Stability Periods
Sterile Water for Injection	30 mg/mL	48 hours
Sterile Water for Injection	up to 20 mg/mL	72 hours
Isotonic Sodium Chloride	30 mg/mL	24 hours
Isotonic Sodium Chloride	up to 20 mg/mL	48 hours
Lactated Ringer's Solution	up to 30 mg/mL	24 hours
5% Dextrose in Water	up to 20 mg/mL	1 hour
5% Dextrose and 0.45% NaCl	up to 10 mg/mL	1 hour

Only those solutions listed above should be used for the intravenous infusion of ampicillin for injection, USP. The concentrations should fall within the range specified. The drug concentration and the rate and volume of the infusion should be adjusted so that the total dose of ampicillin is administered before the drug loses its stability in the solution in use.

CONTRAINDICATION:
Hypersensitivity to the active substance or to any of the excipients.
Ampicillin is penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. ampicillin, penicillin's, cephalosporin's) or excipients.

WARNINGS AND 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

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.

Use in Pregnancy & Lactation
Pregnancy Category B
However, no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Lactation
Ampicillin is excreted in trace amounts in human milk. Therefore, caution should be exercised when ampicillin-class antibiotics are administered to a nursing woman.

ADVERSE EFFECTS
As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins and in those with a history of allergy, asthma, hay fever, or urticaria.
The following adverse reactions have been reported as associated with the use of ampicillin:

Gastrointestinal
Glossitis, stomatitis, black "hairy" tongue, nausea, vomiting, enterocolitis, pseudomembranous colitis, and diarrhea. (These reactions are usually associated with oral dosage forms.)

Hypersensitivity Reactions
Skin rashes and urticaria have been reported frequently. A few cases of exfoliative dermatitis and erythema multiforme have been reported. Anaphylaxis is the most serious reaction experienced and has usually been associated with the parenteral dosage form.
Note: Urticaria, other skin rashes, and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, ampicillin should be discontinued, unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to ampicillin therapy. Serious anaphylactic reactions require the immediate use of epinephrine, oxygen, and intravenous steroids.

Liver – A moderate rise in serum glutamic oxaloacetic transaminase (SGOT) has been noted, particularly in infants, but the significance of this finding is unknown. Mild transitory SGOT elevations have been observed in individuals receiving larger (two to four times) than usual and oft-repeated intramuscular injections. Evidence indicates that glutamic oxaloacetic transaminase (GOT) is released at the site of intramuscular injection of ampicillin sodium and that the presence of increased amounts of this enzyme in the blood does not necessarily indicate liver involvement.
Hemic and Lymphatic Systems – Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported during therapy with the penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.

OVERDOSAGE
In cases of overdose, discontinue medication, treat symptomatically, and institute supportive measures as required. In patients with renal function impairment, ampicillin-class antibiotics can be removed by hemodialysis but not peritoneal dialysis.

Presentation
Ampicillin for Injection, USP is white to off-white crystalline powder supplied in vials containing ampicillin sodium equivalent to 250 mg and 500 mg of ampicillin.
IM & IV USE:
For IM use: Add 1ml sterile water for injection.
For IV use: Add 5ml sterile water for injection.

DIRECTIONS
To be use as directed by the physician.
Protect from light & moisture, store below 25°C.
Keep out of the reach of children.
For suspected adverse drug reaction for BOSCH products, report at ade@bosch-pharma.com

WARNING:
To be sold on prescription of a registered medical practitioner only.

ہدایات برائے استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
25°C سے کم درجہ حرارت پر روشنی اور نمی سے محفوظ رکھیں۔
انجکشن میں کوئی غیر حل پذیر شے نظر آئے تو ہرگز استعمال نہ کریں۔
بچوں کی پہنچ سے دُور رکھیں۔
اغتباہ : صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخے پر فروخت کے لئے۔

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ISO 9001:2015 Certified Company