1. NAME OF THE MEDICINAL PRODUCT

Ampicillin 500 mg powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains ampicillin sodium equivalent to ampicillin 0.5g.

3. PHARMACEUTICAL FORM

Powder for solution for injection/infusion.
A white or almost white powder.

4. CLINICAL PARTICULARS

4.1 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, 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

Posology

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: Intrapleural:	500 mg daily in up to 10 ml water for injections.
Intraarticular:	500 mg daily in 5-10 ml water for injections.
	500 mg daily, in up to 5 ml water for injections 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.

Paediatric population

Half adult routine dosage for children under 10 years.
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.

Method of administration

Intramuscular:	Add 1.5 ml water for injections to 500mg vial contents.
Intravenous:	Dissolve 500 mg in 10 ml water for injections. 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.

3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Ampicillin is a 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. 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).

This medicine contains 33.7 mg of sodium per vial, equivalent to 1.7% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

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.

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.
Breast-feeding
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.

7. Effects on ability to drive and use machines

No studies on the effects to drive and use machines have been performed. Based on reported adverse drug reactions, it is presumed that ampicillin has no or negligible influence on the ability to drive and use machines.

8. Undesirable effects

Hypersensitivity reactions:
If any hypersensitivity reaction occurs, the treatment should be discontinued.
Skin rash, pruritis 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 (see section 4.4) 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 time has also been reported rarely.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the Authority.

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

Ampicillin may be removed from circulation by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Penicillins with extended spectrum, ampicillin
ATC code: J01CA01

Ampicillin is a broad-spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin sensitive organisms.

5.2 Pharmacokinetic properties

Ampicillin is excreted mainly in the bile and urine with a plasma half-life of 1 – 2 hours.

5.3 Preclinical safety data

No further information of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with blood products or other proteinaceous fluids (e.g., protein hydrolysates) or with intravenous lipid emulsions.

6.3 Shelf life

3 years

Shelf-life after preparation of the reconstituted solution
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage conditions and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C -8°C.

The stability of Ampicillin is improved in dilute solutions such as those commonly prepared for intravenous infusion and the drug can be added to most intravenous fluids. Preparation of Ampicillin infusion solutions must be carried out under appropriate aseptic conditions if these extended storage periods are required.

6.4 Special precautions for storage

Do not store above 30°C, store in a cool and dry place. Protect from light
For storage conditions after reconstitution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

7ml molded glass vials, 50 vials/box, 20 boxs/carton

6.6 Special precautions for disposal and other handling

Ampicillin vials are not suitable for multidose use.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Intravenous fluids
Sodium chloride 0.9% with glucose 5% (dextrose saline), 5% glucose, 10% dextran 40 in 5% glucose

M/6 sodium lactate, 1.4% sodium bicarbonate, 10% dextran 40 in normal saline water for injections, sodium chloride 0.9% (normal saline), Ringer's solution

Ampicillin has been shown to be compatible with heparin sodium in intravenous infusions and these agents may be administered concurrently in normal saline.

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.

7. MARKETING AUTHORISATION HOLDER

Advanov Pharma Pvt. Ltd
A/202 Empire Business Hub, Science city road,
Ahmedabad-380060, Gujarat, India

8. MARKETING AUTHORISATION NUMBER(S)

TAN 22 HM 0378

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/09/2022

10. DATE OF REVISION OF THE TEXT

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