Summary of Product Characteristics

1. Name of the medicinal product

Ampicillin Sodium for Injection 0.5g

2. Qualitative and quantitative composition

Ampicillin 500 mg powder for solution for injection/infusion:
One vial contains 531 mg of ampicillin sodium (equivalent to 500 mg ampicillin). For the full list of excipients, see section 6.1.

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

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.

Intraperiton	500 mg daily in up to 10 ml water for
eal:	injections. 500 mg daily in 5-10 ml
Intrapleural:	water for injections.
Intraarticula	500 mg daily, in up to 5 ml water for injections or sterile 0.5% procaine hydrochloride solution.
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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

Intramuscu	Add 1.5 ml water for injections to 500mg vial contents.
lar:	Dissolve 500 mg in 10 ml water for injections. Administer by slow injection (three to four minutes).
Intravenous	Ampicillin may also be added to infusion fluids or injected, suitably diluted, into the drip tube over a period of three to four minutes.
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4.3 Contraindications

A history of a previous hypersensitivity reaction to any of the penicillins is a contraindication.

Ampicillin is a penicillin and should not be give 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).

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.

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.

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.

4.7 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.

4.8 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 of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via the national Pharmacovigilance Electronic Reporting Systems' to the respective national regulatory authorities.;

4.9 Overdose

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:

Antibacterials for systemic use, penicillins with extended

spectrum ATC code: J01CA01.

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.

5.2 Pharmacokinetic properties

Ampicillin for Injection, 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. Due to maturational changes in renal function, ampicillin half-life decreases as postmenstrual age (a sum of gestational age and postnatal age) increases for infants with postnatal age of less than 28 days. The active form appears in the bile in higher concentrations than those found in 16 18 3 4serum. Ampicillin is the least serum-bound of all the penicillins, averaging about 20% compared to approximately 60 to 90% for other penicillins. Ampicillin for Injection, is well tolerated by most patients and has been given in doses of 2 grams daily for many weeks without adverse reactions.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies repeated- dose toxicity and genotoxicity.

Following intravenous administration no teratogenic potential or pre-natal effects were observed in the rat or rabbit. Repeated administration for up to 13 weeks in the rat and dog (2 mg/kg/day) showed no histological effects on the ovary; however, reversible impairment of spermatogenesis was observed in the dog at 200 mg/day. In animal studies at doses higher than those used in humans, ampicillin did not have any adverse effects on fertility.

6. Pharmaceutical particulars

6.1 List of excipients

None

6.2 Incompatibilities

Ampicillin solutions should always be administered separately, unless compatibility with other infusion solutions or medicines has been established.

This medicinal product must not be mixed with other solutions except those mentioned in section 6.6.

Ampicillin solutions should not be mixed with aminoglycosides, metronidazole and injectable tetracycline derivatives such as oxytetracycline, rolitetracycline and doxycycline. Visual signs of incompatibility are precipitation, clouding and discoloration.

6.3 Shelf life

36 months.

Shelf-life after preparation of the ready-to-use solution
Reconstituted/diluted solution should be used immediately.

6.4 Special precautions for storage
Ampicillin should not be stored above 30°C.

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,20boxs/carton.

6.6 Special precautions for disposal and other handling

Ampicillin solutions are compatible with 0.9% (9 mg/ml) sodium chloride solution, 5% (50mg/ml) glucose solution and Ringer solution.

Ampicillin 500 mg powder for solution for injection/infusion

The 10 % injection/infusion solution is prepared by dissolving 0.53 g powder in 5 ml water for injections.

The solutions should always be prepared freshly before use and checked for clarity. Use only clear solutions for injection or infusion! Do not use solutions with cloudiness or precipitation. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Reyoung Pharmaceutical Co., Limited,

No.1 Ruiyang Road, Yiyuan County Shandong, P.R. China.

8. Marketing authorisation number(s)

H2018/CTD5414/358ER/R1

9. Date of first authorisation/renewal of the authorization

24/2/2026

10. Date of revision of the text

24/2/2026