Package Leaflet: Information for the user

Ampicillin 500 mg powder for solution for injection
ampicillin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- Throughout this leaflet Ampicillin 500 mg powder for solution for injection will be referred to as 'Ampicillin injection'.

What is in this leaflet

1. What Ampicillin injection is and what it is used for

Ampicillin injection contains ampicillin which belongs to the penicillin group of antibiotics.

Ampicillin works by killing bacteria that cause infections, such as:
- ear, nose and throat infections
- bronchitis, pneumonia, chest infections
- urinary tract infections
- sexually transmitted infections
- skin and soft tissue infections
- gastrointestinal infections
- blood poisoning.

2. What you need to know before you use Ampicillin injection

Do not use Ampicillin injection:
- if you are allergic to ampicillin, other antibiotics called beta-lactams (e.g. penicillin or cephalosporin) or any of the other ingredients of this medicine (listed in section 6).

If this applies to you, speak to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before using Ampicillin injection:

- if you have ever had a skin rash or swelling of the face or neck when taking any antibiotic
- if you are already being treated with another antibiotic
- if you have glandular fever (mononucleosis) or low immune system
- if you have leukaemia
- if you have kidney problems.

Other medicines and Ampicillin injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by ampicillin or they may affect how well ampicillin will work. Tell your doctor or pharmacist if you are taking:
- any other antibiotics
- allopurinol or probenecid for conditions such as gout
- oral contraceptives (the pill). You will need an additional method of contraception, such as condoms.

Speak to your doctor or pharmacist about how long you need to take extra precautions for.

Urine tests
Tell the doctor if you are having urine tests for glucose, as your medicine may affect the results.

Pregnancy and breast-feeding
Ampicillin will not harm your unborn baby. Small quantities of the medicine may be present in breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
Ampicillin injection is unlikely to affect your ability to operate machinery or to drive.

Ampicillin injection contains sodium
This medicine contains 33.7 mg of sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Ampicillin injection

You will most likely receive Ampicillin injection from a doctor or nurse. Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor or pharmacist if you are not sure.

Your doctor or nurse will usually inject Ampicillin injection into your muscles or veins. Ampicillin injection can also be used in other ways depending on your condition.

The recommended dose is
- **Adults and children over 10 years**: The usual dose is 500 mg four to six times a day. In severe infections the above doses may be increased by your doctor.

- **Patients with kidney problems**: If your kidneys are not working very well, your doctor may change the dose. Your doctor will give you special instructions if you are on kidney dialysis.

Use in children
Children under 10 years: half the adult dose.

If you use more Ampicillin injection than you should:
Having too much Ampicillin is unlikely as the injection will be given to you by a doctor or nurse. However, if you are given too much Ampicillin, you may experience nausea, vomiting and diarrhoea. Ask your doctor or nurse if you have any concerns.

If you forget to use Ampicillin injection
If you think you have missed an injection, speak to your doctor or nurse.

If you stop using Ampicillin injection
Do not stop just because you feel better. If you stop too soon, the infection may come back. Keep having the injection until the prescribed course is finished.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or nurse immediately if you have any of the following **allergic reactions:**
- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps
- blistering of the mouth, eyes, or genital region, patchy areas of rash, peeling skin.

Seek immediate medical attention if you have any of the following symptoms:
- severe stomach cramps, watery and severe diarrhoea which may be bloody, fever
- yellowing of your skin or eyes, pale faeces and dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness
- unusual bleeding or bruising
- fever, sore throat, mouth ulcers, repeated infections or infections that will not go away
- feeling tired, breathless, and looking pale
- fever, rash, nausea, aches and pains, passing more or less urine than usual or passing urine at night.

Some of these reactions may happen several weeks after finishing the treatment.

The following side effects usually settle without changing the dose:
- upset stomach**,** nausea or diarrhoea.

Blood tests: tell your doctor if you are having blood tests as your medicine can cause short-term changes in blood cell counts.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card

Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ampicillin injection

- Keep this medicine out of the sight and reach of children.
- Do not use after the expiry date which is stated on the vial label and on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Once prepared Ampicillin injection should be used immediately. If required, the prepared injection can be stored in a refrigerator (2°C - 8°C) for up to 24 hours.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ampicillin injection contains

- The active substance is ampicillin (500 mg) as ampicillin sodium.
  (See end of Section 2 for further information on sodium).
- There are no other ingredients.

What Ampicillin injection looks like and contents of the pack
Ampicillin is a white powder which is made up into a solution before it is given to you.
It is supplied to doctors in packs of 10 vials.

Marketing Authorisation Holder
Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK.

Manufacturer
Laboratorio Reig Jofre, S.A., C/ Jarama 111, Polígono Industrial Toledo, 45007 Toledo (Spain)

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The following information is intended for healthcare professionals only

Ampicillin 500 mg powder for solution for injection
ampicillin

Content
Ampicillin is available as vials containing the equivalent of 500 mg ampicillin presented as Ampicillin Sodium as a powder for solution for injection.

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, gastrointestinal infections, enteric fever, peritonitis, septicaemia, endocarditis, meningitis.
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, intraarticular, extraperitoneal.

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:	500 mg four times a day IM or IV.
Meningitis:	*Adult dosage*: 2 g six-hourly IV. *Children's dosage*: 150 mg/kg daily IV in divided doses.

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

Intraperitoneal:	500 mg daily in up to 10 ml water for injections.
Intrapleural:	500 mg daily in 5-10 ml water for injections.
Intraarticular:	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 < 10 ml/min) a reduction in dose or extension of dose interval should be considered. In case of dialysis, an additional dose should be administered after the procedure.

Method of administration:
Intramuscular: Add 1.5 ml water for injections to 500 mg 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.

Contra-indications
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).

Special warnings and special 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 dosage section).
Sodium Content: 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.

Interaction with other medicaments 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.

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.

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.

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 Special warnings section) 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 have 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Overdosage
Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically. Ampicillin may be removed from the circulation by haemodialysis.

Pharmacological Properties
Pharmacodynamic properties: Ampicillin is a broad spectrum penicillin, indicated for the treatment of a wide range of bacterial infection caused by ampicillin sensitive organisms.
Pharmacokinetic properties: Ampicillin is excreted mainly in the bile and urine with a plasma half life of one to two hours.
Preclinical safety data: No further information of relevance.

Directions for use
Ampicillin injection is not suitable for multidose use. Any residual Ampicillin solution should be disposed of in accordance with local requirements.

Stability and Compatibility
Shelf-life of the unopened product: 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. Refrigerated solutions should be restored to ambient temperature before use.

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.
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.

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.

Storage	Do not store above 25°C.		
Availability	*Strength* 500 mg	*Packs* 10	*Product Licence* PL 17736/0070
Legal category	POM		
Product Licence Holder	Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, UK		

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