SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ampicillin 125 mg/5ml Oral Suspension

Ampitrin 125 mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of oral suspension contains 125 mg of ampicillin as ampicillin trihydrate Ph.Eur

Excipients with known effect: sodium benzoate, sucrose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for reconstitution into oral suspension.

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. Such indications include infections of the upper and lower respiratory tract including bronchitis and pneumonia, genito-urinary tract and the gastro-intestinal tract, gynaecological infections, septicaemia, peritonitis, endocarditis, meningitis and enteric fever. Specific indications include ear, nose and throat infections and soft tissue infections and gonorrhoea.

Parenteral usage is indicated where oral dosage is inappropriate.

4.2 Posology and method of administration

Usual adult dosage

Ear, nose and throat infections:	250 mg four times a day
Bronchitis:	Routine therapy: 250 mg four times daily
	High dose therapy: 1 g four times daily
Pneumonia:	500 mg four times daily
Urinary tract infections:	500 mg three times daily
Gastro-intestinal infections:	500 - 750 mg three to four times daily
Enteric fevers:	Acute: 1-2 g four times daily for two weeks
	Carriers: 1-2 g four times daily for four to 12 weeks
Gonorrhoea:	2 g orally with 1 g probenecid as a single dose.

Repeated doses are recommended for the treatment of females.

Usual dosage for the elderly:

As for adults; reduced doses may be required in those with impaired renal function.

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 or ampicillin given by injection. Ampicillin should be given a half to one hour before meals.

Consideration should be given to official guidance on the appropriate use of antibacterial agents. Consult local or national prescribing guidelines for antibiotic use before prescribing. Where possible, use only where antibiotic sensitivity is known or suspected.

Renal Impairment:

In severe renal impairment (i.e., creatinine clearance <10 mL/min) reduction in dose or extension of the dose interval should be considered. In patients undergoing dialysis, an additional dose should be administered after dialysis.

Method of administration

For oral administration only

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Use in patients with a history of hypersensitivity to beta lactam antibiotics (penicillins, ampicillin, cephalosporins) or any of the excipients. This product contains Ponceau 4R (E 124). This may cause allergic reactions.

Contains up to 2.0 g of sucrose per dose. This should be taken into account in patients with diabetes mellitus

4.4 Special warning and precautions for use

Prolonged use of an anti-infective may occasionally result in the development of super-infection due to organisms resistant to that anti-infective e.g. Candida or Pseudomonas.

Anaphylactic (anaphylactoid) reactions

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.

Prolonged use may occasionally result in overgrowth of non-susceptible organisms

Use in patients with impaired renal function

Care should be taken with patients with renal impairment and dose adjustment may be required (see section 4.2).

Use in patients with infections

Ampicillin should be avoided if infectious mononucleosis and/or acute and chronic lymphatic leukaemia are suspected as erythematous rashes are more common with these conditions following administration of ampicillin.

Contains sodium benzoate.

4.5 Interaction with other medicinal products and other forms of interaction

Uricosurics: excretion of penicillin is decreased, giving an increased risk of toxicity e.g. Probenecid and sulfinpyrazone.

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 increases the likelihood of ampicillin induced skin reactions.

Anti-coagulants: INR can be altered by the administration of Ampicillin while on Warfarin and Phenindione.

Vaccines: The efficacy of Oral Typhoid Vaccine may be reduced when ampicillin is coadministered

Cytotoxics: the excretion of methotrexate is reduced.

Chloroquine: absorption of ampicillin is reduced when taken concomitantly with chloroquine.

There may be interaction between other bacteriostatic antibacterials such as erythromycin, chloramphenicol and tetracycline as these 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.

Ampicillin may interfere with some diagnostic tests e.g. tests for urinary glucose using copper sulphate, and some tests for urinary or serum proteins. 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

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, 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 (see Item 4.4 – Warnings) 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.

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.

4.9 Overdose

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Beta-lactum antibacterials, penicillins, ATC code: J01CA01

Ampicillin is employed in the treatment of infections of the urinary tract due to gram-negative organisms, especially Escherichia coli, Proteus mirabilis and Enterococci resistant to Benzyl penicillin; it is used for the prophylaxis and the treatment of infections of the respiratory tract such as chronic bronchitis, pneumonia and bronchiectasis.

Because it is excreted in high concentration in the bile it has been used in the treatment of infections of the biliary and intestinal tracts caused by E.coli, Salmonella and Shigellae. Because of its low toxicity and broad anti-microbial spectrum, it has been added to fluids used for intraperitoneal dialysis to prevent the development of bacterial peritonitis.

5.2 Pharmacokinetic properties

Absorption

Ampicillin is relatively stable in the acid gastric secretion and is well absorbed form the gastro-intestinal tract after oral administration. Peak concentrations in serum are obtained in about 1 or 2 hours and are reported to range form 0.8 to 8.5ug per ml.

Distribution

About 20% is bound to plasma proteins in the circulation. It diffuses across the placenta and high concentrations are found in the cerebrospinal fluid when the meanings are infected.

Elimination

About 30% of an orally administered dose is excreted in the urine 6 to 8 hours; urinary concentrations range form 0.25 to 2.5mg per ml. A high concentration is reached in bile.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica
Sodium Benzoate
Sodium Citrate Anhydrous
Croscarmellose sodium
Ponceau 4R (E 124)
Cherry Flavour Powder
Sucrose

6.2 Incompatibilities

None stated

6.3 Shelf life

Unopened: 24 months
Reconstituted: 7 days

6.4 Special precautions for storage

Store in its original container and keep the bottle tightly closed in order to protect from light and moisture.

Dry powder: Store below 25^{o}C.

Reconstituted suspension: Store for 7 days at 2°C-8°C in a refrigerator.

6.5 Nature and contents of container

High density polyethylene bottles with tamper-evident or tamper-evident / child-resistant cap of the appropriate size to accommodate 60ml or 100ml.

May also contain

Hugo Meding – polypropylene spoon – Article number 7229

Or

5ml Medispoon

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

Kent Pharmaceuticals Limited,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 08215/0163

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/03/2009

10 DATE OF REVISION OF THE TEXT

27/03/2026