Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ampicillin Oral Suspension BP 125 mg/5 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of suspension contains Ampicillin Trihydrate equivalent to 125 mg of Ampicillin, as the active substance.

Each 5ml of suspension also contains 7.6 mg of sodium, 0.2 mg of Ponceau 4R (E124) and up to 2.0 g of sucrose.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral suspension
A light pink granular powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Ampicillin Oral Suspension BP is indicated for the oral therapy of bacterial infections caused by ampicillin-sensitive organisms. Such indications include infections of the upper and lower respiratory tract, genito-urinary tract and the gastro-intestinal tract. Specific indications include ear and soft tissue infections and gonorrhoea.

4.2 Posology and method of administration

Usual Adult/Elderly Dosage

The usual dosage is 250 mg every 6 hours

All recommended dosages below are a guide only. In severe infections, the dosages may be increased at the direction of the physician. Doses should be taken 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.

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: 2g orally with 1g probenecid as a single dose. Repeated doses are recommended for the treatment of females.

Usual children's dosage (under the age of 10):

Children may be given half the adult dose.

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.

4.3 Contraindications

Use in patients with hypersensitivity to penicillins or ampicillin cephalosporins or any of the excipients.
This product contains Ponceau 4R (E 124). This may cause allergic reactions. It also contains sucrose.

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.

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.

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

Ampicillin should be avoided Erythematous rashes are common in glandular fever, cytomegalovirus (CMV), and/or acute and chronic lymphatic leukaemia and possibly HIV as erythematous rashes are more common..

Care is necessary when treating spirochaete infections particularly Syphilis.

4.5 Interaction with other medicinal products and other forms of interaction

Ampicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.
Uricosurics: excretion of penicillin is decreased, giving an increased risk of toxicity e.g. *Probenecid* and sulfinpyrazon.

Allopurinol increases 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 ismay 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* may interfere with the bactericidal action of ampicillin.

As *probenecid* prolongs the half-life of this penicillin, it may be used therapeutically for this purpose.

Ampicillin may interfere with some diagnostic tests e.g. tests for urinary glucose using copper sulphate; direct anti-globulin (Coombs' test) and some tests for urinary or serum proteins. Tests using bacteria, e.g. the Guthrie test for phenylketonuria using Bacilus Subtilis organisms, could also be affected while patients are taking penicillins.

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

None.

4.8 Undesirable effects

Side effects as with other penicillins are rare and usually of a mild or transitory nature.

Occasionally, gastro-intestinal disturbances nausea, vomiting and diarrhoea or pseudomembranous colitis may occur.

Erythematous maculo-papular rashes, sore mouth and sore, black, hairy tongue have occurred. Two types of rashes have been observed; an urticarial rash, which is usually indicative of true penicillin hypersensitivity, and an erythematous rash, which is generally specific to ampicillin. The latter is particularly in patients with infectious mononucleosis, cytomegalovirus, acute and chronic lymphatic leukaemia and possibly HIV. Erythema multiforme Stevens Johnson syndrome and toxic epidermal necrolysis has been reported. If a rash occurs, treatment should be discontinued.
Angioedema and anaphylaxis (see section 4.4) have occasionally occurred.

Fever, joint pains, serum sickness-like symptoms have been reported.

There have been reports of haemolytic anaemia, thrombocytopenia, leucopenia, neutropenia and coagulation disorders. Prolongation of bleeding time and prothrombin time have also been reported rarely.

Particularly with high doses or in renal impairment, CNS toxicity including convulsions have occurred; with prolonged use paraesthesia.

Nephropathy and interstitial nephritis have been reported.

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.

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

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 benzylpenicillin; it is used for the prophylaxis and treatment 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 antimicrobial spectrum, it has been added to fluids used for intra peritoneal dialysis to prevent the development of bacterial peritonitis.

5.2 Pharmacokinetic properties

Ampicillin is relatively stable in the acid gastric secretion and is moderately well absorbed from the gastro-intestinal tract after oral administration. Peak concentrations in serum are obtained in about 1 or 2 hours and are reported to range from 0.8 to 8.5 microgram per ml. About 20% is bound to plasma proteins in the circulation. It diffuses across the placenta and high concentrations are found in cerebrospinal fluid when the meninges are infected. About 30% of an orally administered dose is excreted in the urine in 6 to 8 hours; urinary concentrations range from 0.25 to 2.5 mg 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 (E211)
Sodium citrate anhydrous
Carmellose Sodium
Ponceau 4R (E124)
Cherry flavour powder 17.41.0086
Sucrose

6.2 Incompatibilities

None known.

6.3 Shelf Life

Unopened: 2 years.

After reconstitution: 7 days.

6.4 Special precautions for storage

Dry Powder: Store below 25^{o}C.
Keep the container tightly closed in order to protect from moisture.

Reconstituted Suspension: Store in a refrigerator (at 2-8 ^{o}C).
Store in the original container.

6.5 Nature and contents of container

60 ml and 100 ml natural high density polyethylene bottles with white plastic tamper evident caps.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

To reconstitute:
(a) Add 76 mls of water to obtain 100 mls of suspension.
(b) Add 46 mls of water to obtain 60 mls of suspension.
Appearance on reconstitution: A red syrup with a cherry odour and flavour.

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Athlone Laboratories Limited
Ballymurray
Co. Roscommon
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 298/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 July 1986

Date of last renewal: 04 July 2006

10 DATE OF REVISION OF THE TEXT

October 2010