

SUMMARY OF PRODUCT CHARACTERISTICS

1 TRADE NAME OF THE MEDICINAL PRODUCT

Ampicillin Syrup BP 250 mg **and** Ampitrin

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of syrup contains 250 mg of ampicillin as ampicillin trihydrate Ph.Eur

3 PHARMACEUTICAL FORM

Powder for reconstitution into syrup.

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, 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 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. 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.

For oral administration only

4.3 Contraindications

Use in patients with a history of hypersensitivity to penicillins, or 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 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.

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 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.

4.5 Interaction with other medicaments and other form 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 sulfinpyrazone.

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 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 may interfere with the bactericidal action of ampicillin.

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

4.6 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 stated

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. Pseudomembranous 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.

4.9 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.

5 PHARMACOLOGICAL PARTICULARS

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 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

Ampicillin is relatively stable in the acid gastric secretion and is well absorbed from the gastrointestinal 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 µg per ml. 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 meninges are infected. About 30% of an orally administered dose is excreted in the urine 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

Aerosil (Silica)
Sodium Benzoate

Sodium Citrate Anhydrous
Sodium Carboxymethylcellulose
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 below 25°C. Protect from light and moisture.

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 100ml.

May also contain

Hugo Meding – polypropylene spoon – Article number 7229
Or
5ml Medispoon

6.6 Instructions for use/ handling

No special instructions

7 MARKETING AUTHORISATION HOLDER

Athlone Laboratories Limited,
Ballymurray,
Co. Roscommon,
Ireland.

8 MARKETING AUTHORISATION NUMBER

PL 6453/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

First granted: 07/07/88
Renewed 26/01/94

10 DATE OF PARTIAL REVISION OF TEXT

10/04/2012