SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ampicillin 500mg Capsules **and**
Ampitrin 500mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 500 mg of ampicillin as ampicillin trihydrate Ph. Eur

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsules

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, 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 at the direction of the physician. 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, penicillins, beta-lactam antibiotics, cephalosporins or to any of the excipients listed in section 6.1.

4.4 Special warnings 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.

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.

4.5 Interaction with other medicinal products 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.

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 may interfere with the bactericidal action of ampicillin.

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, 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, 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 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

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 PARTICULARS

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Beta-lactam antibiotic, 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

Absorbtion
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 meninges 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

Magnesium Stearate
Capsule shell
Black Iron Oxide E172
Titanium Dioxide E171
Patent Blue V E131
Quinoline Yellow E104
Erythrosine E127

6.2 INCOMPATABILITIES

None stated

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25^{o}C in a dry place.

6.5 NATURE AND CONTENTS OF CONTAINER

Polypropylene securitainer with polyethylene air-proof cap 15, 18, 20, 21, 28, 30, 50, 100 or 500 capsules
Or an
Opaque PVC/PVDC blister 250/40 with a 20 micron aluminium lidding foil containing 15, 16, 18, 20, 21, 28, 30, 50, 100 or 500 capsules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORIZATION HOLDER

Athlone Laboratories Limited,
Ballymurray,
Co. Roscommon,
Ireland

8 MARKETING AUTHORIZATION NUMBER

PL 6453/0008

9 DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

First granted 24/4/87. Renewed 24/4/92.

10 DATE OF REVISION OF THE TEXT

20/08/2014