

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ampicillin Capsules BP 250 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Ampicillin trihydrate BP equivalent to 250 mg of Ampicillin.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ampicillin capsules are presented as size 2, black/pink opaque capsules printed with "AMP 250" on one side and company logo on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Parenteral usage is indicated where oral dosage is inappropriate. Ampicillin is a broad-spectrum antibacterial indicated for treatment of commonly occurring bacterial infections where a sensitive organism is suspected or proven.

Lower respiratory tract - acute and chronic bronchitis, lobar and bronchopneumonia.

Upper respiratory tract - bacterial pharyngitis, otitis media, chronic bronchial sepsis.

Genito- urinary tract - acute cystitis, pyelonephritis for sensitive infections, gonorrhoea (in combination with probenecid.) and gynaecological infections.

Other - skin and soft tissue infections, dental abscess (as an adjunct to surgical management), enteric fever, intra-abdominal sepsis, peritonitis and septicaemia (in combination with an aminoglycoside or metronidazole).

Other infections including, endocarditis and meningitis.

Ampicillin is inactivated by penicillinases including those produced by *Staphylococcus aureus* and gram-negative bacteria such as *E.coli*.

4.2 Posology and method of administration

Posology

Usual adult dosage

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

Usual dosage for the elderly

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

Usual dosage in paediatric population (children 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. Oral doses of ampicillin 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.

Renal Impairment:

In the presence of severe renal impairment (creatinine clearance <10ml/min) a reduction in dose or extension of dose interval should be considered. In cases of dialysis, an additional dose should be administered after the procedure.

Method of administration

Route of administration: Oral

4.3 Contraindications

Ampicillin should not be given to patients with a history of penicillin hypersensitivity or hypersensitivity to beta-lactam antibiotics (e.g. Ampicillin, penicillins, 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 overgrowth of non-susceptible organisms 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 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 the administration of ampicillin.

Use in patients with impaired renal function

Care should be taken and dosage should be adjusted in patients with renal impairment (see section 4.2).

Sodium

This medicine contains less than 1mmol sodium (23 mg) per capsule, that is to say essentially "sodium free".

4.5 Interaction with other medicinal products and other forms of interaction

Phenindione and warfarin: INR can be altered by a course of oral broad-spectrum antibacterials such as ampicillin.

Methotrexate excretion is reduced by penicillins.

Absorption of ampicillin is reduced when taken concomitantly with chloroquine.

Probenecid and sulfinpyrazone decreases penicillin excretion. Concurrent use with ampicillin may result in increased and prolonged blood levels of ampicillin; giving an increased risk of toxicity.

The efficacy of the oral typhoid vaccine may be reduced when ampicillin is co-administered.

Bacteriostatic drugs such as erythromycin, chloramphenicol and tetracycline may interfere with the bactericidal action of ampicillin.

Concurrent administration of allopurinol during treatment with ampicillin can increase the likelihood of allergic skin reactions.

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.

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. Ampicillin has been in extensive clinical use since 1961 and suitability in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, Ampicillin may be considered appropriate.

Breastfeeding:

Trace quantities of ampicillin can be detected in breast milk.

Adequate human and animal data on the use of Ampicillin during lactation are not available.

4.7 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects

Side effects are mainly of a mild and transitory nature.

Gastro-intestinal reactions:

Effects include diarrhoea, vomiting, and nausea. Pseudomembraneous colitis and haemorrhagic colitis have been reported occasionally.

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 has 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.

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-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 antimicrobial 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 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 8.5ug 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 from 0.25 to 2.5mg per ml. A high concentration is reached in bile.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Starch Glycolate

Magnesium Stearate

Capsule Body

Erythrosine (E127)

Titanium Dioxide (E171)
Water
Sodium Laurilsulfate
Gelatin
Capsule Cap
Black Iron Oxide (E172)
Titanium Dioxide (E171)
Water
Sodium Laurilsulfate
Gelatin
Printing Ink
Titanium Dioxide (E171)
Polyoxyethylene 20 Sorbitan Mono-oleate
Shellac

6.2 Incompatibilities

None stated.

6.3 Shelf life

Opaque plastic containers: 48 months.
Blister packing: 24 months.

6.4 Special precautions for storage

Protect from heat, light and moisture.

6.5 Nature and contents of container

Ampicillin capsules are packed in the following containers and closures.

1. Opaque plastic containers (securitainers) with plastic caps in pack sizes of 9, 10, 14, 15, 20, 21, 28, 30, 50, 56, 84, 100, 250, 500 and 1000 capsules.
2. Opaque plastic containers composed of either high density polypropylene with a tamper evident or child resistant tamper evident closure composed of high density polyethylene for all pack sizes (9, 10, 14, 15, 20, 21, 28, 30, 50, 56, 84, 100, 250, 500 and 1000) with a packing inclusion of standard polyether foam or polyethylene or polypropylene made filler.
3. Blister packs of aluminium/opaque PVC. It is subsequently packed in printed boxboard cartons in pack sizes of 9, 10, 14, 15, 20, 21, 28, 30, 56 and 84.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special instructions for use/handling.

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Ltd.,
Key House,
Sarum Hill, Basingstoke,
RG21 8SR, UK.

8. MARKETING AUTHORISATION NUMBER

PL 20416/0012

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

23/01/2009

10 DATE OF REVISION OF THE TEXT

08/05/2024