



**National Agency for Food & Drug
Administration &
Control (NAFDAC)**

**Registration & Regulatory Affairs (R & R)
Directorate**

**SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC)
TEMPLATE**

[Instructions in this font/colour are from the World Health Organisation Public Assessment

Report WHOPAR guidelines.]

[Additional instructions and examples]

{<example text>}

1. Name of the medicinal product

Ampicillin 500mg Capsules

2. Qualitative and quantitative composition

(Ampicillin Capsules): 500mg ampicillin as Ampicillin Trihydrate

3. Pharmaceutical form

Black and red capsules overprinted Penbritin 500

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. Typical indications include: ear, nose and throat infections, bronchitis, pneumonia, urinary tract infections, gonorrhoea, gynaecological infections, septicaemia, peritonitis, endocarditis, meningitis, enteric fever, gastro-intestinal infections.

Parenteral usage is indicated where oral dosage is inappropriate.

4.2 Posology and method of administration

Usual adult dosage (including elderly patients):

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

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. Oral doses of ampicillin should be taken half to one hour before meals.

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.

4.3 Contraindications

Ampicillin is a penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. ampicillin, penicillins, cephalosporins) or excipients.

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.

Ampicillin should be avoided if infectious mononucleosis and/or acute or chronic leukaemia of lymphoid origin are suspected. The occurrence of a skin rash has been associated with these conditions following the administration of ampicillin.

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

Dosage should be adjusted in patients with renal impairment (see section 4.2).

4.5 Interaction with other medicinal products and other forms of interaction

Bacteriostatic drugs 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.

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 can increase the likelihood of allergic skin reactions.

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 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

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

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 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 have 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.

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

Ampicillin is a broad spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by ampicillin sensitive organisms.

5.2 Pharmacokinetic properties

Ampicillin is excreted mainly in the bile and urine with a plasma half life of 1-2 hours.

5.3 Preclinical safety data

No further information of relevance to add.

6. Pharmaceutical particulars

6.1 List of excipients

Magnesium stearate, gelatin, black and red iron oxides (E172), titanium dioxide (E171) and erythrosine (E127).

6.2 Incompatibilities

None.

6.3 Shelf life

Blister packs: five years

Others: three years

6.4 Special precautions for storage

Containers: Do not store above 25°C. Keep the container tightly closed.

Blisters: Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Aluminium canister

Glass bottle fitted with a screw cap

Polypropylene tube with a polyethylene closure - 4, 16, 50, 100, 500

Aluminium/PVC blister pack - 28.

6.6 Special precautions for disposal and other handling

None.

7. Applicant / manufacturer :

JIANGXI XIER KANGTAI PHARMACEUTICAL CO., LTD.

Add: North Zone, High New-Tech Industrial Zone, Pingxiang City, Jiangxi Province, China.

8. Marketing authorisation number(s)

Gan20160103

9. Date of first authorisation/renewal of the authorisation

30th Dec. 2020

10. Date of revision of the text

01/11/2021
