

# PAMECIL

## 1. NAME OF THE MEDICINAL PRODUCT

PAMECIL 250mg hard capsules

PAMECIL 500mg hard capsules

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PAMECIL 250mg: Each capsule contains 250mg ampicillin as ampicillin trihydrate

PAMECIL 500mg: Each capsule contains 500mg ampicillin as ampicillin trihydrate

## 3. PHARMACEUTICAL FORM

PAMECIL 250mg: Black-Scarlet hard gelatin capsule size "2"

PAMECIL 500mg: Black-Scarlet hard gelatin capsule size "0", [elongated](#)

## 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

#### Posology

#### ***Dosage for Adults and Elderly patients***

<i>Ear, Nose, Throat infections</i>	: 250mg four times a day
<i>Bronchitis</i>	: Routine therapy 250mg four times a day
<i>Pneumonia</i>	: 500mg four times a day
<i>Urinary tract infections</i>	: 500mg three times a day
<i>Gastrointestinal infections</i>	: 500 to 750mg three to four times daily
<i>Enteric infections</i>	: <i>Acute:</i> 1-2g four times a day for two weeks. <i>Carries:</i> 1-2g four times a day for four to twelve weeks.
<i>Gonorrhoea</i>	: 2g orally with 1g of probenecid as a single dose. Repeated doses are recommended for the treatment of females.

#### ***Paediatric population***

Children less than 10 years old: 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.

#### ***Renal Impairment***

In the presence of severe renal impairment (creatinine clearance less than 10 ml/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

PAMECIL capsules are administered orally.

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

### 4.3. Contraindications

Hypersensitivity to the active substance, 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**

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. Interactions 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. 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

##### Breast-feeding

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 section 4.4) 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.

**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 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,

**6.2. Incompatibilities**

None.

**6.3. Shelf life**

24 months.

**6.4. Special precautions for storage**

Store below 30°C in the original package

**6.5. Nature and Contents of Container**

[PVC-PVDC Al blisters.](#)

Cartons of 500 & 1000 capsules are available.

Not all pack sizes may be marketed.

**6.6. Special precautions for disposal**

No special requirements.

**7. MARKETING AUTHORISATION HOLDER**

KOMEDIC SDN BHD, 4 Jalan PJS 11/14, Bandar Sunway, 46150 Petaling Jaya

**8. MANUFACTURER**

MEDOCHEMIE LTD., Factory B, 48 Iapetou Street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol, Cyprus

**9. MARKETING AUTHORISATION NUMBER**

PAMECIL 250mg hard capsules: MAL19860391AZ

PAMECIL 500mg hard capsules: MAL19860396AZ

**10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

PAMECIL 250mg hard capsules: 08/05/2002

PAMECIL 500mg hard capsules: 08/05/2002

**11. DATE OF REVISION OF THE TEXT**

12/2021