



MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the Medicinal Product

LAMPICIN CAPSULES

2. Qualitative and Quantitative Composition

- Each capsule contains Ampicillin Trihydrate B.P Equivalent to Ampicillin 250mg.

For excipients, see 6.1

4. Pharmaceutical Form

Capsules

Description: Red coloured bodu and black coloured cap hard gelatin capsules, having printed with “LAMPICIN” and ‘250’ on the cap and body alternatively, containing almost white powder.

5. Clinical Particulars

5.1 Therapeutic Indications

LAMPICIN is 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.

5.2 Posology and method of administration

Dosage for genitourinary tract infections or gonorrhoea

Adult dosage (ages 18–64 years)

For genitourinary tract infections other than gonorrhoea:

- Typical dosage is 500 mg four times per day.
- Severe or chronic infections may require larger doses.

For gonorrhoea:

- Typical dosage is 3.5 grams once, with 1 gram of probenecid.

Child dosage (children who weigh more than 20 kg)

For genitourinary tract infections other than gonorrhoea:

- Typical dosage is 500 mg four times per day.

Child dosage (children who weigh 20 kg or less)

For genitourinary tract infections:

- Typical dosage is 100 mg/kg per day in four equally divided and spaced doses.

For gonorrhoea:

- Typical dosage is 3.5 grams as a single dose.

Child dosage (children who weigh less than 20 kg)

For genitourinary tract infections:

- Typical dosage is 100 mg/kg per day in four equally divided and spaced doses.

Senior dosage (ages 65 years and older)

The kidneys of older adults may not work as well as they used to. This can cause your body to process drugs more slowly. As a result, more of a drug stays in your body for a longer time. This raises your risk of side effects.

Your doctor may start you on a lowered dosage or a different schedule. This can help keep levels of this drug from building up too much in your body.

Dosage for respiratory tract infections

Adult dosage (ages 18–64 years)

- Typical dosage is 250 mg four times per day.

Child dosage (children ages 0–17 years who weigh more than 20 kg)

- Typical dosage is 250 mg four times per day.

Child dosage (children ages 0–17 years who weigh 20 kg or less)

- Typical dosage is 50 mg/kg per day in equally divided and spaced doses three to four times per day.

Senior dosage (ages 65 years and older)

The kidneys of older adults may not work as well as they used to. This can cause your body to process drugs more slowly. As a result, more of a drug stays in your body for a longer time. This raises your risk of side effects.

Your doctor may start you on a lowered dosage or a different schedule. This can help keep levels of this drug from building up too much in your body.

Dosage for gastrointestinal tract infections

Adult dosage (ages 18–64 years)

- Typical dosage is 500 mg four times per day.
- Typical dosage is 500 mg four times per day.

Child dosage (children who weigh more than 20 kg)

- Typical dosage is 500 mg four times per day.

Child dosage (children who weigh 20 kg or less)

- Typical dosage is 100 mg/kg per day in four equally divided and spaced doses.

Senior dosage (ages 65 years and older)

The kidneys of older adults may not work as well as they used to. This can cause your body to process drugs more slowly. As a result, more of a drug stays in your body for a longer time. This raises your risk of side effects.

Your doctor may start you on a lowered dosage or a different schedule. This can help keep levels of this drug from building up too much in your body.

Dosage for meningitis

Adult dosage (ages 18–64 years)

Your doctor will decide the dosage that's right for you.

Child dosage (ages 0–17 years)

Your child's doctor will decide the dosage that's right for your child.

Senior dosage (ages 65 years and older)

The kidneys of older adults may not work as well as they used to. This can cause your body to process drugs more slowly. As a result, more of a drug stays in your body for a longer time. This raises your risk of side effects.

Your doctor may start you on a lowered dosage or a different schedule. This can help keep levels of this drug from building up too much in your body.

OR

As directed by the Physician.

5.3 Contraindications

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

5.4 Special warnings and precautions for use

Ampicillin is distributed to liver, bile, muscle, kidney, crop, and fat following absorption from the GI or injection site. Ampicillin has been used therapeutically and prophylactically for avian salmonellosis with promising results. ... Ampicillin is excreted in bile.

5.5 Interaction with other medicinal products for use

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.

5.6 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.

5.7 Effects on ability to drive and use machines

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

5.8 Undesirable effect

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 authorization 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 reaction.

5.9 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.

6. PHARMACOLOGICAL PROPERTIES

6.1 Pharmacodynamics

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

6.2 Pharmacokinetics

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

7. PHARMACEUTICAL PARTICULARS

7.1 List of excipients

Magnesium Stearate
Starch
Empty hard gelatin capsule

7.2 Incompatibilities

Not Applicable

7.3 Shelf life

24 months

7.4 Special precautions for storage

Store in a cool dry place at temperature below 30°C. Store in the original packaging.

7.5 Nature and contents of container

Available in blister packs of 10 x 10s

7.6 Special precautions for disposal and other handling

None

7. Marketing authorization holder

Me Cure Industries PLC
Plot 6 Block H, Debo Industries Compound,
Oshodi Industrial Scheme,
Oshodi,
Lagos,
Nigeria.

8.0 NAFDAC REGISTRATION NUMBER: 04-4930