MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the Medicinal Product
Lampicin Oral Suspension

2. Qualitative and Quantitative Composition
Ampicillin 125mg Dry Syrup Powder
Each 5ml from the bottle contains Ampicillin 125mg as Ampicillin Trihydrate.

For excipients, see 6.1

3. Pharmaceutical Form
Oral powder for constitution.

4. Clinical Particulars

4.1 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.
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4.2 Posology and method of administration

Children: Up to 2 years, 2.5ml every 6 hours
Children: 2 to 6 years, 5ml every 6 hours
Children: 6 to 12 years, 5 – 10ml every 6 hours
OR
As directed by the Physician.

4.3 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.

4.4 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.

4.5 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.

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 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. Pseudomembraneous 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.

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 Pharmacodynamics

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

5.2 Pharmacokinetics

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

LAMPICIN 125mg/5ml Suspension:
Sodium Benzoate
Sodium CMC (HVP)
Colloidal Anhydrous Silica
Sodium citrate
Flavor Raspberry
Neomalt
Colour Sunset Yellow

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

100ml Pet bottle containing 30g of Ampicillin powder.

6.6 Special precautions for disposal and other handling

None

7. Marketing authorization holder

Me Cure Industries Limited

Plot 6 Block H, Debo Industries Compound,

Oshodi Industrial Scheme,

Oshodi,

Lagos,

Nigeria.

8.0 NAFDAC REGISTRATION NUMBER: A4-3948