

## Summary of Product Characteristics

### 1.0 NAME OF THE MEDICINAL PRODUCT

Emcillin suspension 125mg/5ml

### 2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml suspension contains Ampicillin 125mg

### 3.0 PHARMACEUTICAL FORM

Powder for oral suspension.

Product Distribution Category: Prescription Only Medicine(POM)

### 4.0 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, and gastrointestinal infections. Extraperitoneal application of Ampicillin to wounds can be used to prevent infection following abdominal surgery. Parenteral usage is indicated where the oral dosage is inappropriate.

#### 4.2 Posology

Usual adult dosage (including elderly patients): Ampicillin may also be administered by other routes of conjunction with systemic therapy.

Septicaemia, endocarditis, osteomyelitis: 500 mg four to six times a day IM or IV for one to six weeks.

Peritonitis, intra-abdominal sepsis:

500mg four times a day IM or IV.

Meningitis:

Adult dosage: 2 g six-hourly IV.

Children dosage: 150 mg/kg daily IV in divided doses.

Intraperitoneal: 500 mg daily in up to 10 ml water for injections.

Intrapleural: 500 mg daily in 5-10 ml water for injections.

Intraarticular: 500 mg daily, in up to 5 ml water for injections or sterile 0.5% procaine hydrochloride solution

Local use in abdominal surgery: 1 g sterile powder sprinkled into the wound extraperitoneally or into muscle layers to prevent wound infection post operatively.

Paediatric population Half adult routine dosage for children under 10 years.

All recommended dosages are a guide only. In severe infections the above dosages may be increased.

Renal Impairment In the presence of severe renal impairment (creatinine clearanceLocal

### **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). It should not be given to patients with glandular fever or acute lymphatic leukaemia.

### **4.4 Special warnings and special 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.

### **4.5 Interaction with other medicinal products and other forms of Interaction**

If ampicillin is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions.

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. Methotrexate excretion is reduced by penicillins.

### **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 for Injection 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.

While adverse effects are apparently rare, three potential problems exist for the nursing infant:

- modification of bowel flora.
- direct effects on the infant such as allergy/sensitisation.
- interference with interpretation of culture results when a pyrexia of unknown origin occurs.

### **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**

The following convention has been used for the classification of undesirable effects in terms of frequency

Skin and subcutaneous tissue disorders

Common: skin rash, pruritus and urticaria. The incidence is higher in patients suffering from infectious mononucleosis and acute or chronic leukaemia of lymphoid origin. Purpura has also been reported.

Uncommon: skin reactions such as erythema multiforme (Stevens-Johnson syndrome), and toxic epidermal necrolysis have been reported.

Rare: anaphylaxis

Renal and urinary disorders

Uncommon: Interstitial nephritis

Gastrointestinal disorders:

Common: nausea, vomiting and diarrhoea.

Uncommon: Pseudomembranous colitis and haemorrhagic colitis.

Hepatobiliary disorders

Common: a moderate and transient increase in

Transaminase

Uncommon: hepatitis and cholestatic

Jaundice

Blood and lymphatic system disorders:

Uncommon: haematological effects including transient leucopenia, transient thrombocytopenia and haemolytic anaemia. Prolongation of bleeding time and prothrombin.

#### **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 properties**

Pharmacotherapeutic group: Beta-lactam antibacterials, penicillins

##### Mode of action

Ampicillin is an aminopenicillin that has a bactericidal action due to its inhibition of the synthesis of the bacterial cell wall.

##### Mechanism of resistance

Bacteria may be resistant to ampicillin due to production of beta-lactamases which hydrolyse aminopenicillins, due to alteration in penicillin-binding proteins, due to impermeability to the drug, or due to drug efflux pumps.

One or more of these mechanisms may co-exist in the same organism, leading to variable and unpredictable cross-resistance to other beta-lactams and to antibacterial drugs of other classes.

## Breakpoints

The MIC breakpoints for susceptible organisms vary according to species.

### Susceptibility:

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections.

As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

### Commonly susceptible species

#### Gram positive aerobes

*Listeria monocytogenes*,

*Streptococcus agalactiae*,

*Streptococcus pyogenes*.

#### Gram negative aerobes

*Neisseria meningitidis*

#### Anaerobes

*Bacteroides* spp

*Clostridium* spp

*Fusobacterium* spp

*Peptostreptococci*

Species for which acquired resistance may be a problem

#### Gram positive aerobes:

*Enterococcus faecalis*,

*Streptococcus pneumoniae*,

#### Gram negative aerobes

*Escherichia coli*

*Haemophilus influenzae*

*Haemophilus parainfluenzae*,

*Moraxella catarrhalis*,

*Neisseria gonorrhoeae*,

*Proteus* spp.,

*Salmonella* spp,

*Shigella* spp

Inherently resistant organisms

Gram negative aerobes: Acinetobacter spp, Citrobacter spp, Enterobacter spp, Klebsiella spp  
Pseudomonas spp, Serratia spp,

Others

Chlamydia Mycoplasma Legionella

## **5.2. Pharmacokinetic properties**

Following the intramuscular administration of 500 mg, ampicillin reaches peak plasma concentrations within about 1 hour which are reported to range from 7 to 14 µg/ml. Ampicillin is widely distributed and therapeutic concentrations can be achieved in ascitic, pleural and joint fluids.

Ampicillin is around 20% bound to plasma proteins and the plasma half-life is about 1 to 1½ hours. Ampicillin is metabolised to some extent to penicilloic acid which is excreted in the urine. Renal clearance of ampicillin occurs partly by glomerular filtration and partly by tubular secretion; it is retarded by the concomitant administration of probenecid. Following parenteral administration, about 60 to 80% is excreted in the urine within 6 hours. Ampicillin is removed by haemodialysis. High concentrations are reached in bile, it undergoes enterohepatic recycling and some is excreted in the faeces.

## **5.3 Preclinical safety data**

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

# **6. PHARMACEUTICAL PARTICULARS**

## **6.1 List of Excipients**

None

## **6.2. Incompatibilities**

If Ampicillin is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set; because loss of activity of the aminoglycoside can occur under these conditions. Ampicillin should not be mixed with blood products or other proteinaceous fluids (e.g. protein hydrolysates) or with intravenous lipid emulsions.

## **6.3. Shelf life**

Unopened vial: 3 years. After reconstitution: From a microbiological point of view, the reconstituted product should be used immediately, unless reconstitution has taken place in controlled and validated aseptic conditions.

## **6.4. Special precautions for storage**

Unopened: Preserve the tightly closed containers, stored in cool and dry place, not exceeding 30°C. Protect from light. Keep out of reach of children.

After Reconstitution: The reconstituted product should be used immediately unless reconstitution has taken place in controlled and validated aseptic conditions.

## **6.5. Nature and contents of the container**

Bottle pack of 100ml

## **6.6. Special precautions for disposal and other handling**

Not applicable

The vials are not suitable for multidose use. All solutions should be shaken vigorously before injection and administered immediately after reconstitution. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7.0 Marketing Authorization Holder**

Emzor Pharmaceuticals Limited, Plot 3C, Block A Aswani market road Oshodi-Isole expressway,Lagos.

**8. Marketing authorisation number(s)**

NA

Manufacturer

Emzor Pharmaceuticals Limited

Lagos State.

**9. Date of first authorisation/renewal of the authorisation**

NA

**10. Date of revision of the text**

NA