1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product

- Product name: Impilin Capsules
- Strength: Each capsule contains Ampicillin 250 mg
- Pharmaceutical form: Capsule, hard

2. Qualitative and quantitative composition

Each hard capsule contains the following:

Ampicillin trihydrate equivalent to Ampicillin	250 mg
Magnesium stearate	5 mg

3. Pharmaceutical form

Capsule, hard Red and black capsules - IMPILIN 250 printed in white colour on the cap & IMPILIN 250 printed in yellow colour on the body

4. Clinical Particulars

4.1. Therapeutic indications

Infections of the upper and lower respiratory tract, genitourinary tract, gastrointestinal tract, Ear, Nose and Throat infection, and gonorrhea due to susceptible strains. Specifically, mastoiditis, gynecological infections, septicemia, peritonitis, endocarditis, meningitis, cholecystitis, osteomyelitis

4.2. Posology and method of administration

Adults, including the elderly: 250mg – 1g p.o 6 hourly or as the physician directs.

The usual doses for each illness are:
Ear, nose and throat: 250mg four times daily
Bronchitis: 250mg four times daily. This may be increased to 1 gram four times daily in some instances.
Pneumonia: 500mg four times daily

Urinary tract infections: 500mg three times daily
Gastrointestinal infections: 500 - 750mg three to four times daily.
Typhoid fevers: Acute: 1 - 2 grams four times daily for 2 weeks Carriers: 1 - 2 grams four times daily for 4 to 12 weeks

Gonorrhea: 2 grams orally with 1 gram of Probenecid as a single dose. A repeated dose may be necessary in females. The dosage may be reduced in patients with severe kidney failure.

Children: under 10 years. Children usually take half the adult dose

The dosage may be reduced in patients with severe kidney failure.

4.3. Contraindication

History of hypersensitivity to penicillin, cephalosporins, and penicillin derivatives.

4.4. Special warnings and precautions for use

Keep all medicines out of the reach of children. Before initiating therapy with ampicillin, careful enquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics.
Prolonged use of antibiotics may occasionally result in superinfection development due to organisms resistant to that antibiotic. The drug should be discontinued in case of superinfections with mycotic or bacterial pathogens (usually Enterobacter, Pseudomonas or Candida).
Periodic renal, hepatic and hematopoietic functions assessment should be made during prolonged therapy.
Ampicillin should be avoided if infectious mononucleosis and/or acute and chronic lymphatic leukemia are suspected, as erythematous rashes are common with this condition following the administration of ampicillin.

4.5. Interaction with other medical products and other forms of interaction

Ampicillin may reduce the absorption and efficacy of oral contraceptives, and patients should be warned accordingly.

Concurrent use of uricosurics leads to decreased excretion of ampicillin, increasing the risk of toxicity, e.g. Probenecid and sulfinpyrazone.

Allopurinol increases ampicillin-induced skin reactions.

The efficacy of the Oral Typhoid Vaccine may be reduced when ampicillin is co-administered, and the excretion of methotrexate is reduced.

Absorption of ampicillin is reduced when taken concomitantly with chloroquine.

Bacteriostatic drugs such as erythromycin, chloramphenicol and tetracycline may interfere with the bactericidal action of ampicillin.

Ampicillin may interfere with some diagnostic tests, e.g. tests for urinary glucose using copper sulphate and some tests for urinary or serum proteins.

4.6 Fertility, Pregnancy and Lactation

Ampicillin has been assigned to pregnancy category B. There are no controlled data on human pregnancy. However, the majority of retrospective data available indicate that ampicillin is not likely to be a human teratogen. Ampicillin is only recommended for use during pregnancy when the benefit outweighs the risk.

Substantial information indicates that ampicillin produces low levels in milk that are not expected to cause adverse effects in breastfed infants. Occasionally, disruption of the infant's gastrointestinal flora, resulting in diarrhoea or thrush, has been reported with penicillin, but these effects have not been adequately evaluated. Ampicillin is acceptable in nursing mothers.

4.7 Effects on the ability to drive and use machine

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects (e.g., allergic reactions, dizziness, convulsions) may influence the ability to drive and use machines. Do not drive or operate machinery if you experience these side effects.

4.8 Undesirable effects

Nausea, vomiting and diarrhoea. Urticaria, skin rashes and serum sickness. Purpura, skin reactions such as erythema multiforme, Steven-Johnson syndrome and toxic epidermal necrolysis have been reported. Rarely, anaphylaxis, interstitial nephritis, pseudo-membranous colitis and hemorrhagic colitis, hepatitis, cholestatic jaundice and a moderate and transient increase in transaminases have been reported. Transient leucopenia, transient thrombocytopenia and hemolytic anemia, prolongation of bleeding time and prothrombin.

4.9. Overdose

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures as required. In patients with renal function impairment, ampicillin-class antibiotics can be removed by hemodialysis, not peritoneal dialysis. Treatment is symptomatic and supportive.

5. Pharmacological properties

Ampicillin is bactericidal at low concentrations and is clinically effective against gram-positive organisms, usually susceptible to penicillin G and against various gram-negative organisms. It is stable in gastric acid and is well absorbed from the gastrointestinal tract. It diffuses readily into most body tissues and fluids; however, penetration into the cerebrospinal fluid and brain occurs only with meningeal inflammation. Ampicillin is mainly excreted unchanged in the urine; its excretion can be delayed by concurrent administration of Probenecid, which inhibits the renal tubular secretion of ampicillin. In blood serum, ampicillin is the least bound of all the penicillins; an average of about 20 per cent of the drug is bound to the plasma proteins as compared to 60 to 90 per cent of the other penicillins. The administration of a 500 mg dose of ampicillin trihydrate capsules results in an average peak blood serum level of approximately 3.0 mcg/mL; the average peak serum level for a 250 mg dose of ampicillin trihydrate for oral suspension is approximately 2.3 mcg/mL.

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Beta-lactam antibacterial, Penicillins with extended-spectrum

ATC code: J01CA01

Ampicillin is a semi-synthetic derivative of penicillin that functions as an orally active broad-spectrum antibiotic. Ampicillin is a bactericidal antibiotic that interferes with the formation of new bacterial cell walls by dividing organisms. Mechanism of resistance: The primary mechanism of resistance to Impilin is an alteration of penicillin-binding proteins (PBPs), which reduces the affinity of the antibacterial agent for the target.

Pharmacodynamic effects

Antibiotic action: Ampicillin is bactericidal; it adheres to bacterial penicillin-binding proteins, inhibiting bacterial cell wall synthesis. The spectrum of activity includes non-penicillinase-producing gram-positive bacteria. It's also effective against many gram-negative organisms, including *Neisseria gonorrhoeae, Neisseria meningitidis, Haemophilus influenza, Escherichia coli, Proteus mirabilis, Salmonella* species, and *Shigella* species. Ampicillin should only be used in gram-negative systemic infections when organism sensitivity is known.

5.2. Pharmacokinetic properties

Absorption: About 42% of ampicillin is absorbed after an oral dose.

Distribution: Distributed into pleural, peritoneal, and synovial fluids, lungs, prostate, liver, and gallbladder; it also penetrates middle ear effusions, maxillary sinus and bronchial secretions, tonsils, and sputum. Readily crosses the placental barrier; minimally protein-bound (15% to 25%).

Metabolism: Only partially metabolized.

Excretion: Excreted in urine by renal tubular secretion and glomerular filtration. It also appears in breast milk. Elimination half-life is about 1 to 11/2 hours; in patients with extensive renal impairment, half-life is extended to 10 to 24 hours.

6. Preclinical safety data

N/A

6.1. List of excipients

Magnesium stearate

6.2. Incompatibilities

Not Applicable

6.3. Shelf life

24 months

6.4. Special precautions for storage

It should be stored below 30°C away from direct sunlight

6.5. Nature and contents of container

Capsules packed in blisters made of aluminium foils which are then packed in cartons

6.6. Special precautions for disposal and other handling

The product should be kept away from the reach of children. After the treatment, the remaining medicine should be discarded or returned to the pharmacist.

7. Marketing Authorization Holder

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8. MAH No/ License: 04-2283

9. Date of first Authorization/renewal of the authorization: 4/08/011

10. Date of revision of the text: 20/09/23