1.3.1 Summary of Product Characteristics

1.3.1.1. Name of the medicinal product

- Product name: Imox Capsules
- Strength: Each capsule contains Amoxicillin 500 mg
- Pharmaceutical form: Capsule, hard

1.3.1.2. Qualitative and quantitative composition

Each hard capsule contains Amoxicillin trihydrate 500mg

Magnesium stearate q.s

1.3.1.3. Pharmaceutical form

Capsule, hard

Yellow and maroon capsules. IMOX 500 print with White colour on cap & IMOX 500 print with Black colour on body.

1.3.1.4. Clinical particulars

1.3.1.4.1. Therapeutic indications

Amoxicillin is indicated for the treatment of the following bacterial infections caused by susceptible organisms: Infections of the upper respiratory tract, including infections of the ears, nose and throat: Acute otitis media, acute sinusitis and bacterial pharyngitis. Infections of the lower respiratory tract: Acute exacerbation of chronic bronchitis, community-acquired pneumonia, otitis media, dental abscess and other oral infections. Infections of the lower urinary tract: Cystitis. Prophylaxis of endocarditis in patients at risk i.e. surgery in the oral cavity or upper airways, osteomyelitis, Lyme disease, post-splenectomy prophylaxis, gynaecological infections, gonorrhea, Helicobacter pylori eradication, anthrax.

1.3.1.4.2. Posology and method of administration

Imox capsules can be taken with or without food. The dose of Amoxicillin selected to treat an individual infection should take into account the expected pathogens and their likely susceptibility. In patients with renal impairment, the dose should be adjusted according to the degree of impairment. Standard adult dosage (≥ 40kg) One capsule (500mg) every 8 hours

'OR' As directed by the Physician.

1.3.1.4.3. Contraindication

Imox capsule is contraindicated in individuals with a history of hypersensitivity reaction to penicillin, Amoxicillin, Penicillin derivatives or any of the Cephalosporins or any of the beta lactams and patients with infectious mononucleosis.

1.3.1.4.4. Special warnings and precautions for use

Before initiating therapy with Imox capsules, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents. Convulsions may occur in patients with impaired renal function or in those receiving high doses or in patients with predisposing factors (e.g. history of seizures, treated epilepsy or meningeal disorders.

In patients with renal impairment, the dose should be adjusted according to the degree of impairment.

Imox capsules should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.

Periodic assessment of organ system functions; including renal, hepatic and haematopoietic function is advisable during prolonged therapy.

Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin. So, appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

During the administration of high doses of Imox capsules, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria.

The presence of amoxicillin may distort assay results for oestriol in pregnant women.

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

<u>Probenecid</u>

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increased and prolonged blood levels of amoxicillin.

<u>Allopurinol</u>

Concurrent administration of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.

Tetracyclines

Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxicillin.

Oral anticoagulants

Oral anticoagulants and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, the physician should adjust the dose of oral anticoagulants accordingly.

Methotrexate

Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

1.3.1.4.6 Fertility, Pregnancy and lactation

1.3.1.4.7 Effects on ability to drive and use machine

1.3.1.4.8. Adverse effects

Imox capsule is generally well tolerated. Hypersensitivity reactions presenting as skin rash, pruritus, urticaria, Angio-oedema, Anaphylaxis, erythema multiforma, Stevens-Johnson syndrome and exfoliative dermatitis. If a rash occurs, treatment should be discontinued. Others are blood dyscrasias, diarrhoea, nausea, vomiting, neuromuscular hypersensitivity, pseudomembraneous colitis.

1.3.1.4.9. Overdose

In case of overdose, gastrointestinal symptoms and disturbance of the fluid and electrolyte balance may be evident. They may be treated symptomatically and supportive with attention to the water/electrolyte balance. In the absence of an adequate fluid intake and urinary output, crystallurria is a possibility and the antibiotic may be removed from the circulation by heamodialysis.

1.3.1.5. Pharmacological properties, ATC code

Amoxicillin is a broad-spectrum semisynthetic antibiotic similar to ampicillin except that its resistance to gastric acid permits higher serum levels with oral administration. Amoxicillin is commonly prescribed with clavulanic acid (a beta lactamase inhibitor) as it is susceptible to beta-lactamase degradation.

1.3.1.5.1. Pharmacodynamic properties

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

ATC code: J01CA04

Amoxicillin is similar to penicillin in its bactericidal action against susceptible bacteria during the stage of active multiplication. It acts through the inhibition of cell wall biosynthesis that leads to the death of the bacteria. Amoxicillin is broad spectrum antibiotic with activity against gram-negative and gram-positive bacteria.

Mechanism of resistance: The main mechanism of resistance to Amoxicillin is inactivation by bacterial beta-lactamases. The other is alteration of penicillin-binding proteins (PBPs), which reduce the affinity of the antibacterial agent for the target.

Pharmacodynamic effects

1.3.1.5.2. Pharmacokinetic properties

Pharmacokinetics

Absorption

Amoxicillin is stable in the presence of gastric acid and is rapidly absorbed after oral administration. The effect of food on the absorption of amoxicillin from Imox capsules has been studied only when administered at the start of a light meal.

Orally administered dose of 500-mg amoxicillin capsule results in average peak blood levels 1 to 2 hours after administration in the range of 5.5 mcg/mL to 7.5 mcg/mL.

Distribution

Amoxicillin diffuses readily into most body tissues and fluids, with the exception of brain and spinal fluid, except when meninges are inflamed. In blood serum, amoxicillin is approximately 20% protein-bound. Following a 1-gram dose and utilizing a special skin window technique to determine levels of the antibiotic, it was noted that therapeutic levels were found in the interstitial fluid.

Metabolism and Excretion

The half-life of amoxicillin is 61.3 minutes. Approximately 60% of an orally administered dose of amoxicillin is excreted in the urine within 6 to 8 hours. Detectable serum levels are observed up to 8 hours after an orally administered dose of amoxicillin. Since most of the amoxicillin is excreted unchanged in the urine, its excretion can be delayed by concurrent administration of probenecid

1.3.1.6 Preclinical safety data /pharmaceutical particulars

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

Carcinogenicity studies have not been conducted with amoxicillin.

1.3.1.6.1. List of excipients

Capsule content:

Magnesium stearate

Capsule shell:

Gelatin, Sodium Lauryl Sulphate (SLS), Methyl Paraben, Propyl Paraben

Printing ink:

Brilliant Blue, Ponceau 4R, Titanium dioxide, Sunset Yellow, Tartrazine

1.3.1.6.2. Incompatibilities

Not applicable.

1.3.1.6.3. Shelf life

24 months

1.3.1.6.4. Special precautions for storage

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

1.3.1.6.5. Nature and contents of container

Capsules packed in blisters made of aluminum foils which are then packed in cartons made of paper.

1.3.1.6.6. Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

1.3.1.7. MAH

Applicant: CHRIS-EJIK PHARMACEUTICALS & HEALTH CARE PRODUCTS LTD.

Address: 3, OJE-IMIANVAN STREET, OFF OREGUN ROAD, IKEJA, P.O. BOX 6768, LAGOS STATE, NIGERIA.

Tel : +234 8150892289, +234 9066000006

E-mail : info@chrisejik.com

1.3.1.8. MAH no/License

Manufacturer's name: CHRIS-EJIK PHARMACEUTICALS & HEALTH CARE PRODUCTS LTD.

Physical address: 3, OJE-IMIANVAN STREET, OFF OREGUN ROAD, IKEJA, LAGOS STATE, NIGERIA.

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1.3.1.9 Date of first authorization/renewal of authorisation

1.3.1.10 Date of revision of the text

1.3.1.11 Dosimetry