1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Annclox Suspension

(Ampicillin BP 125 mg and Cloxacillin BP 125 mg powder for oral suspension)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains :

Ampicillin as Ampicillin Trihydrate BP….125 mg

Cloxacillin as Cloxacillin Sodium BP……125 mg

3. PHARMACEUTICAL FORM

Powder for oral Suspension

A white powder filled in HDPE bottle which turns yellow suspension on reconstitution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Annclox is indicated for the treatment of bacterial infections i.e. Respiratory tract infections, urinary tract infections, skin and soft tissue infections, specticaemia, pelvic infections, ear, nose and throat infections, Gonnorrhea, Typhoid and Paratyphoid infections.

4.2 Posology and method of administration

Always take Annclox suspension exactly as your doctor has told you and always read the label. Your doctor will decide on the appropriate dose to suit your condition. Ask your doctor pharmacist if you are not sure.

The powder should be reconstituted immediately before use, by adding freshly boiled and cooled water to the mark on the bottle (For Annclox Neonatal oral drops) and 70 ml of freshly boiled and cooled water to the powder (For Annclox Suspension) respectively. The contents should be mixed thoroughly to produce a uniform suspension.

Shake the bottle well before the administration of each dose of the medicine. Take the suspension an hour before or two hours after a meal.

Once reconstituted, the suspension should be used within seven (7) days.

DOSES

Neonates: Use the Calibrated dropper provided.

Administer: 0.6- 1.0 ml, every 4-6 hours, half to one hour prior to feeding.

Children:

2 years- 5years: 5-10 ml (1-2 Teaspoonful) every 6 hours.

1 month -2 years: 2.5-5 ml (Half -One Teaspoonhtl), every 6 hours.

4.3 Contraindications:

Annclox should not be given to patients with known hypersensitivity to the penicillin or cephalosporin. Cases of cross sensitivity have been reported. It should not be given to babies born of hypersensitive mothers in the neonatal period. It should be not be given to patient with infectious mononucleosis, lymphatic leukemia. HIV Infection or myasthenia gravis. It should be given with care to patients with poor renal function.

The oral dosage forms are not recommended for chronic, severe, or deep-seated infections such as sub-acute bacteria endocarditis, meningitis or syphilis. Annclox should not be administered by Sub-conjunctiva injection or used as an eye drop as it contains Cloxacillin.

4.4 Special warnings and precautions for use:

Special care must be taken with Annclox suspension, especially in patients-taking other antibacterial which are bacteriostatic in mode of action.

Annclox Should not be administered concomitantly) with other antibacterial drugs that are bacteriostatic in nature.

Care should be taken when high doses are given to patients with renal impairment (because of the risk of neurotoxicity) or congestive heart failure. Renal and haematological systems should be monitored during prolonged and high dose therapy,

Care should be taken when treating patients with syphilis, as the Jarisch-Herxheimer reaction may occur shortly after starting treatment. This reaction, manifesting as fever, chills, headache and reactions at the site of the lesion, can be dangerous in cardiovascular syphilis or where there is a serious risk of increased local damage such as with optic atrophy.

Haemolytic anaemia and leucopenia, prolongation of bleeding time and defective platelet function have been observed usually following high intravenous doses.

Convulsions and other signs of toxicity to the CNS may occur particularly with intravenous administration or in patients with renal failure.

Intrathecal administration of pcnici1lins is not recommended, because it is a potent convulsant when given by this route.

Annclox contains Ampicillin and should preferably not be given to patients with infectious mononucleosis, lymphatic leukaemia and patients receiving allopurinol treatment because of an increased risk of developing skin rashes.

Annclox may decrease the efficacy of oestrogen-containing oral contaceptives.

Annclox contains Cloxacillin sodium; therefore disturbances of blood electrolytes may follow the administration of large doses.

Warning: Annclox may cause anaphylactic reactions in patients intolerant to penicillin. Do not administer to babies and children who are allergic to penicillin or cephalosporin.

Important information about some of the ingredients of ANNCLOX (Ampicillin+ Cloxacillin) suspension:

Sucrose: This should be taken into account in patients with diabetes mellitus.

4.5 Interaction with other medicinal products and other forms of interaction

Annclox suspension should not be taken with the following drugs to prevent drug to drug interaction: - Allopurinol, Antacids, Chloroquine, Oral contraceptives, probenecid, Tetracycline, Warfarin, Phenytoin.

4.6 Pregnancy and lactation

Pregnancy: Annclox suspension is a drug that is administered to neonates, Its use in pregnancy therefore may be considered to be safe.

Breast-feeding: Annclox suspension is a drug that is administered to neonates. Its use in breast feeding mothers therefore may be considered to be safe.

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

Like all medicines, Annclox suspension can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Annclox may produce diarrhoea, nausea and heartburn. Allergic reactions which may include exfoliative dermatitis, other skin rashes, interstitial nephritis and vasculitis may occur. In this

event, withdrawal of Annclox and administration of an antihistamine will suffice in most cases. Should a serious anaphylactic reaction occur. Annclox should be discontinued and the patient treated with the usual agents (adrenalin, corticosteroids or antihistamines).

A generalized sensitivity reaction with urticaria, fever, joint pains and eosinophilia can develop within a few hours to several weeks after starting treatment.

Super infection by penicillin resistant species, such as Pseudomonas or Candida, may occur especially with prolonged use.

A sore mouth or tongue and a black hairy tongue have been reported.

Increase in liver enzyme values have been reported.

4.9 Overdose

Taking an overdose of the suspension can be harmful**.** See side effects and precautions.

1. Tell your doctor, pharmacist or nearest hospital casually department immediately.
2. Take the bottle and any remaining suspension with you so that people can see what you have taken.
3. Do this even if the patient feels well.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ampicillin Trihydrate is an oral antibiotic, active against a wide range of Gram-negative and Gram-positive organisms.

Ampicillin and Cloxacillin is a penicillin antibiotic combination often prescribed to provide an extended spectrum of efficacy, particularly against penicillin-resistant infections.

It is prescribed for the treatment of a wide range of bacterial infections caused by susceptible organisms including middle ear infections, upper and lower respiratory tract infections, gastro-intestinal infections, skin and soft-tissue infections such as boils or infections as a result of spider bites, impetigo - a bacterial skin infection characterized by small pus-filled blisters, and endocarditis - inflammation of the lining of the heart and its valves.

This penicillin-combination can cause minor stomach upsets and a blotchy skin rash, a common unwanted effect which is not necessarily an indication of an allergic reaction. Should you develop a skin rash you should however consult your doctor to rule out the possibility of allergy. A penicillin allergy may lead to fever, swelling of the mouth and tongue, itching and associated breathing difficulties.

5.2 Pharmacokinetic properties

Absorption: The oral administration of 250 mg and 500 mg of Ampicillin on a fasting stomach produces maximum serum levels of ± 2 and ± 4 mcg per ml, respectively, after 2 hours. Bioavailability is 30 to 40%. The absorption of orally administered Ampicillin can be diminished by food. Distribution: Serum protein binding Ampicillin is about 20 %. Plasma half-life is between 1 and 1 ½ hours. Ampicillin diffuses into most tissues and body fluids. Its presence in therapeutic concentrations has been detected in, among others, bronchial secretions sinuses, saliva, CSF (variable percentage depending on the degree of meningeal inflammation), bile, serous membranes and middle ear. Crosses the meningeal barrier: There is little ampicillin diffusion into the cerebrospinal fluid, except in cases of inflamed meninges, in which it can reach therapeutic concentrations when administered in high doses and especially by the intravenous route. Cross the placenta: Ampicillin diffuses through the placenta. Passes into mother's milk: Ampicillin is detected in small quantities in mothers' milk. Metabolism and Excretion: Ampicillin is eliminated chiefly through the urine. Approximately 30% of the dose administered orally and over 60 % of the dose administered parenterally are eliminated in active form in the urine during the 24 hours which follow the administration of Ampicillin. Urinary concentrations are higher following parenterally administration. A small percentage is eliminated in the bile where high concentrations are found. Excretion may be delayed in cases of renal failure in accordance with its severity.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

6. Pharmaceutical particulars

6.1 List of excipients

Aerosil 200
Citric Acid
Methyl Paraben
Propyl Paraben
Sodium Citrate
Sodium CMC (MVP)
Sugar Pharmagrade

Colour tartrazine supra

Dry Flavour Peppermint

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in cool and dry place, Temperature below 30^0C. Protect from Moisture.

6.5 Nature and contents of container

100 ml HDPE White Bottle

7. MARKETING AUTHORISATION HOLDER

ANNIE PHARMA LIMITED

Plot 6 Abimbola Street, Isolo Industrial Estate, Isolo, Lagos, Nigeria

E-mail: contactus@jawasil.com

8. MANUFACTURED BY:

JAWA INTERNATIONAL LIMITED

Plot 6 Abimbola Street, Isolo Industrial Estate, Isolo, Lagos, Nigeria

Phone: +2348073894283. E-mail: contactus@jawasil.com

9. MARKETING AUTHORISATION NUMBER(S)

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10. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

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11. DATE OF REVISION OF THE TEXT

July 26, 2018

Legal Classification

POM: Prescription Only Medicine

Not to be sold without the prescription of a Registered Medical Practitioner.