1.3.3 Package Insert (also known as patient information PIL)

Enclosed

ANNCLOX (POWDER FOR SUSPENSION / DROPS)

COMPOSITION

A. Each 0.6ml of Annclox Neonatal Oral Drops Contains Ampicillin BP 60mg and Cloxacillin BP 30mg
B. Each 5ml of Annclox oral Suspension contains: Ampicillin BP 125mg + Cloxacillin BP 125mg

CLINICAL PHARMACOLOGY

Mechanism of Action

Annclox is a broad spectrum formulation of Ampicilin and penicillinase stable Cloxacillin. It exhibits bactericidal activity against a wide range of Gram-positive and Gram-negative organisms, such as streptococcus species, staphylococcus species salmonella species etc.

INDICATIONS

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

CONTRA-INDICATIONS

Annclox should not be given to patients with known hypersensitivity to the penicillins or cephalosporins. 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 leukaemia. 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-conjunctival injection or used as an eye drop as it contains Cloxacillin.

DOSAGE AND 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 or 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 70ml 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 – 1.0ml, every 4 – 6 hours, half to one hour prior to feeding.

Children:
2 years - 5years: 5 – 10ml (1 – 2 Teaspoonful) every 6 hours
1 month – 2 years: 2.5 – 5ml (Half – One Teaspoonful), every 6 hours.

SIDE 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 generalised 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.

PRECAUTIONS.

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 penicillins 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.

WARNINGS

Annclox may cause anaphylactic reactions in patients intolerant to penicillins. Do not administer to babies and children who are allergic to penicillins or cephalosporins.

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

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

USE IN PREGNANCY AND BREAST-FEEDING

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.

INTERACTIONS

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.

OVERDOSAGE AND TREATMENT

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

1. Tell your doctor, pharmacist or nearest hospital casualty 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.

STORAGE

Keep in a cool, dry place, below 30°C. Container should be tightly closed.
Protect from heat and direct sunlight. Do not freeze.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN
SHAKE THE BOTTLE BEFORE USE.

PRESENTATION

Annclox Neonatal Oral Drops and Annclox Oral Suspension are presented in 8ml and 100ml Pilfer proofed bottles respectively, as a dry powder that is reconstituted shortly before use.

Manufactured by:
JAWA INTERNATIONAL LIMITED
Plot 6, Abimbola Way,
Isolo Industrial Estate,
Isolo, Lagos, Nigeria.

Marketed by:
ANNIE PHARMA LIMITED
Jawa house Compound
Plot 6, Abimbola Way,
Isolo Industrial Estate,
Isolo, Lagos.