1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Annclox neonatal drops

(Ampicillin BP 60 mg and Cloxacillin BP 30 mg for oral suspension)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.6 ml contains :

Ampicillin as Ampicillin Trihydrate BP….60 mg

Cloxacillin as Cloxacillin Sodium BP……30 mg

3. PHARMACEUTICAL FORM

Powder for oral Suspension

A white powder filled in a glass bottle which turns yellow on reconstitution, packed in a 20 ml Amber glass bottle.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Respiratory tract infections, Ear, Nose and Throat infections, Urinary tract infections, Gastro-intestinal infections, Skin and Soft Tissue infections, Pelvic infections, Septicaemia, Endocarditis, Orthopaedic infections.

4.2 Posology and method of administration

Adults and children over 10 : 500 mg –1 g (1 –2 x 500 mg capsules) every 6 hours.

Children 2 –10 years : 250 –500 mg (5 –10 mL of 250 mg/5 mL syrup) every 6 hours.

Children up to 2 years : 250 mg (5 mL of 250 mg/5 mL syrup) every 6 hours.

Neonates : 90 mg (0,6 mL i.e. to mark on pipette) every 4 hours.

4.3 Contraindications:

Ampicillin is penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. ampicillin, penicillins, cephalosporins) or excipients.

4.4 Special warnings and 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 pencillins. These reactions are more likely to occur in individuals with a history of beta-lactam hypersensitivity. Ampicillin should be avoided if infectious mononucleosis and/or acute or chronic leukaemia of lymphoid origin are suspected. The occurrence of a skin rash has been associated with these conditions following the administration of ampicillin. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. Dosage should be adjusted in patients with renal impairment.

4.5 Interaction with other medicinal products and other forms of interaction

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.

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 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.

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

Hypersensitivity reactions: If any hypersensitivity reaction occurs, the treatment should be discontinued. Skin rash, pruritis and urticaria have been reported occasionally. The incidence is higher in patients suffering from infectious mononucleosis and acute or chronic leukaemia of lymphoid origin. Purpura has also been reported. Rarely, skin reactions such as erythema multiforme and StevensJohnson syndrome, and toxic epidermal necrolysis have been reported. As with other antibiotics, anaphylaxis (see Item 4.4 – Warnings) has been reported rarely. Renal effects: Interstitial nephritis can occur rarely. Gastrointestinal reactions: Effects include nausea, vomiting and diarrhoea. Pseudomembraneous colitis and haemorrhagic colitis has been reported rarely. Hepatic effects: As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely. As with most other antibiotics, a moderate and transient increase in transaminases has been reported. Haematological effects: As with other beta-lactams, haematological effects including transient leucopenia, transient thrombocytopenia and haemolytic anaemia have been reported rarely. Prolongation of bleeding time and prothrombin have also been reported rarely. Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

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 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 characterised 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 parenteral 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

Sodium saccharin

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

20 ml Amber glass 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.