### 1.3.3 Package Insert (also known as patient information PIL)

Enclosed

# ANNMOX
## POWDER FOR SUSPENSION / DROPS

**COMPOSITION**
Each 1ml of Annmox Neonatal Oral Drops Contains Amoxicillin BP 100mg
Each 5ml of Annmox Oral Suspension contains: Amoxicillin BP 125mg

**CLINICAL PHARMACOLOGY**
Amoxicillin like ampicillin is a beta lactam semi-synthetic penicillin. However absorption of Annmox syrup from the gastro-intestinal tract is better than that of ampicillin, peak plasma concentrations are reached within 2 hours.
Annmox syrup has action against gram positive organisms including Streptococcus species and other streptococci. It is also active against gram negative organisms such as Moraxella, Neisseria gonorrhoea, N. meningitides and E. coli.
Annmox syrup is resistant to acid inactivation in gastric secretions and its bioavailability is not diminished by the presence of food.

**Mechanism of Action**
Annmox is a broad spectrum formulation of Amoxicillin. It exhibits bactericidal activity against a wide range of Gram-positive and Gram–negative organisms.

**INDICATIONS**
Annmox is indicated for the treatment of bacterial infections; Billiary Tract Infections, Bronchitis, Endocarditis, Gastro – Enteritis (including E. coli Enteritis, Salmonella Enteritis, but not Shigellosis), Otitis Media, Mouth Infections, Pneumonia, Typhoid and Paratyphoid fever, Urinary Tract Infections, Bone and Joint Infections and Skin and Soft Tissue infections.

**CONTRA-INDICATIONS**
Annmox should not be given to patients with known hypersensitivity to 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 not be given to patients with infectious mononucleosis, lymphatic leukaemia, HIV Infection or myasthenia gravis. It should be given with care to patients with poor renal function.

**DOSAGE AND ADMINISTRATION**
Always take Annmox 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 of the bottle (For Annmox Neonatal oral drops) and 70ml of freshly boiled and cooled water to the powder (For Annmox 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.
≤ 3months; 30mg/kg per day given every 12 hours.
Administer 0.6 - 1.0ml, every 4 - 6 hours, half to one hour prior to feeding.
**Children:**
**For Bacterial Infections:**
≥ 3 months; 20 - 40mg/kg per day given every 8hours OR 25 - 45mg/kg per day given every 12 hours.
2 years - 10 years: 5 - 10ml (1 - 2 Teaspoonful), every 8 hours
1 month - 2 year: 2.5 - 5ml (Half - One Teaspoonful), every 8 hours.

**SIDE EFFECTS**
Like all medicines, Annmox 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.
Common side effects include nausea, vomiting and diarrhoea.
Severe side effects include
- Bloody or watery stools with or without stomach cramps.
- Severe allergic reaction with symptoms such as swelling of the tongue and throat, difficult breathing, swelling of hands, feet and other body parts.
- Severe Skin rash.
- Yellowing of the child's skin and the whites of the eyes. This can be a sign of liver problems.
- Brown, yellow or grey staining of the child's teeth.
- Unusual bleeding and bruising.

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

**WARNINGS**
Annmox 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 ANNMOX (Amoxicillin) suspension:**
**Sucrose:** This should be taken into account in patients with diabetes mellitus.

**USE IN PREGNANCY AND BREAST-FEEDING**
**Pregnancy**
Annmox suspension is a drug that is administered to neonates. Its use in pregnancy therefore may be considered to be safe.
**Breast-feeding**
Annmox suspension is a drug that is administered to neonates. Its use in breast feeding mothers therefore may be considered to be safe.

**INTERACTIONS**
**Annmox** interacts with certain drugs such as birth control pills, Probenecid, Warfarin, other antibiotics such as Doxycycline and Tetracycline.

**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**
STORE IN A COOL, DRY PLACE, BELOW 30°C. CONTAINER SHOULD BE TIGHTLY CLOSED.
PROTECT FROM MOISTURE, HEAT AND DIRECT SUNLIGHT. DO NOT FREEZE.

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

**PRESENTATION**
Annmox Neonatal Oral Drops and Annmox Oral Suspension are presented in 10ml & 100ml Pilfer proofed bottles respectively, as a dry powder that is reconstituted immediately before use.

*Manufactured by:*
**JAWA INTERNATIONAL LIMITED**
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*Marketed by:*
**ANNIE PHARMA LIMITED**
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