1.3.1.1 PROPOSED PACKAGE INSERT

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM**):**

MOXYPEN-250 (Capsules)

MOXYPEN-500 (Capsules)

MOXYPEN 125 mg/5 ml (Powder for suspension)

MOXYPEN 250 mg/5 ml (Powder for suspension)

COMPOSITION:

Capsules containing amoxycillin trihydrate equivalent to Amoxycillin 250 mg and 500 mg, and powder for preparing fruit-flavoured suspensions. When dispensed as directed, each 5 ml of the suspension contains amoxycillin trihydrate equivalent to 125 mg or 250 mg amoxycillin. The powder contains 0,1 % m/v sodium benzoate B.P. as a preservative.
THE CAPSULES ARE SUGAR FREE. THE POWDER FOR SUSPENSION CONTAINS SUGAR.

MOXYPEN-250 and **MOXYPEN-500** excipients: Erythrosine, dimethicone USNF, gelatin capsule, indigo carmine, magnesium stearate, polyplasdone XL (povidone), shellac USNF, sodium lauryl sulphate and titanium dioxide.

MOXYPEN 125 mg/5 ml and **MOXYPEN 250 mg/ 5 ml** other excipients: Disodium edentate, flavour orange trusil, sodium citrate, dried, and sucrose.

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.2 Penicillins

PHARMACOLOGICAL ACTION:

Amoxycillin is a penicillinase-susceptible semisynthetic penicillin. It is bactericidal *in vitro* against a broad spectrum of gram-positive and gram-negative pathogens. Being acid stable amoxycillin is well absorbed when given orally. Peak plasma concentrations are reached at 2 hours and average about 4 µg/ml when 250 mg is administered.

The *in vitro* antibacterial spectrum of **MOXYPEN** is as follows (*in vitro* sensitivity does not necessarily imply *in vivo* efficacy).

MOXYPEN is particularly active *in vitro* against the following organisms:

- Gram positive organisms: *Streptococcus pneumoniae**, *Streptococcus faecalis** (enterococci), *Streptococcus agalactiae* (group B), penicillin-sensitive *Neisseria gonorrhoeae, Listeria monocytogenes.*

MOXYPEN is also active *in vitro* against the following organisms:

- Gram positive organisms: *Staphylococcus aureus** (penicillin-sensitive), *Streptococcus pyogenes, Streptococcus viridans**, *Streptococcus bovis, Neisseria menningitidis* (except the carrier state), *Bacillus antracis**, Corynebacterium species*, Clostridium species*.

MOXYPEN also has *in vitro* activity against the following gram-negative organisms (these organisms may produce beta-lactamase):

- *Escherichia coli**, *Heamophilus influenza** (except type b-strains causing meningitis in children), Samonella* and Shigella* species. (Note that amoxycillin is less active in vitro against Shigella than ampicillin).

MOXYPEN may also have some effect against the following organisms:

- Bacteroides fragilis*, Proteus mirabilis* and Nocardia*.

*Sensitivity tests must be formed.

Most species of the following organisms are resistant to **MOXYPEN**:

Enterobacter, Pseudomonas, Klebsiella, Serratia, Acinetobacter and indole-positive Proteus.

INDICATIONS:

Infections caused by susceptible, non-penicillinase-producing organisms including:

- Respiratory tract infections (upper and lower): sinusitis, phyrngitis, epiglottitis, acute and chronic bronchitis and acute typical pneumonia.
- Otitis media;
- Urinary tract infections;
- Uncomplicated gonococcal infections;
- Meningitis (sensitivity tests must be performed);
- Gastro intestinal infections including salmonella and typhoid;
- Uncomplicated gastro enteritis and enteric fever;
- Miscellaneous: Skin and soft tissue infections, bacteremia and as adjunct in the treatment of sepsis caused by gram-negative bacteria.

CONTRA-INDICATIONS:

Patients known to be sensitive to penicillins or cephalosporins.

Should not be given to patients with infectious mononucleosis, since they are especially susceptible to amoxycillin-induced skin rashes, patients with lymphatic leukaemia and patients with hyperuricaemia being treated with allopurinol, may be at increased risk of developing skin rashes.

WARNINGS AND SPECIAL PRECAUTIONS:

MOXYPEN should be used with caution in patients with syphilis, as the Jarisch-Herxheimer reaction may occur.

INTERACTIONS:

MOXYPEN may decrease the efficacy of oestrogen-containing oral contraceptives.

MOXYPEN may affect the absorption of other medicines, due to its effect on the gastro intestinal flora.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years:

250 mg of amoxycillin three times a day; 500 mg of amoxycillin may be required in some severe infections.

In gonorrhea the usual dose is the equivalent of 3 g given as a single dose, usually combined with 1 g probenecid.

To reconstitute:

100 ml suspension: Add 59 ml water, invert bottle and shake well until all the powder is dissolved.

75 ml suspension: Add 44,25 ml water, invert bottle and shake well until all the powder is dissolved. (Hospital pack).

Children:

The normal dose for children 6 months to 10 years of age is equivalent of 125 mg (i.e. 5 ml of 125 mg/5 ml) three times a day.

0 – 6 months: 62,5 mg three times a day.

SIDE-EFFECTS:

Supra-infections with non-susceptible organisms, for example with Candida and Pseudomonas, may occur.

Pseudomembranous colitis has been reported.

Allergic reactions can occur in persons sensitised to penicillins, presenting with a pruritic skin rash, an erythematous skin reaction or urticaria.

Should a serious anaphylactic reaction occur, **MOXYPEN** should be discontinued and the patient treated with adrenaline, corticosteroids and antihistamines.

Gastro intestinal discomfort, diarrhoea, nausea and vomiting may occur.

Reduced doses may be required in patients with impaired renal function.

Raised serum transaminase concentrations have been reported.

Other adverse effects that have been reported include photosensitivity, blood dyscrasias such as neutropenia and pancytopenia and auditory and visual hallucinations.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "SIDE EFFECTS". Treatment is symptomatic and supportive.

IDENTIFICATION:

250 mg capsules: White granules filled in size "2" hard gelatin capsule comprising a mauve body and blue cap printed circular in white ink "**MOXYPEN 250"** on cap and body.

500 mg capsules: White granules filled in size "0EL" hard gelatin capsule comprising a mauve body and blue cap printed circular in white ink "**MOXYPEN 500"** on cap and body.

Suspensions: A white to off-white, free-flowing powder, which when reconstituted as directed, forms a white to off-white suspension.

PRESENTATION:

Capsules:

15 capsules: HDPE containers or blister packs.

100 capsules: HDPE or polypropylene containers.

Suspensions:

Bottles containing powder for reconstitution to 75 ml and 100 ml of 125 mg/5 ml or 250 mg/5 ml suspension.

STORAGE INSTRUCTIONS:

Containers should be kept tightly closed and stored at or below 25 °C.

Once dispensed, the suspensions must be used within 7 days when stored at or below 25 °C, or within 14 days when stored in a refrigerator (below 7 °C).

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

250 mg Capsules: M/20.1.2/293

500 mg Capsules: M/20.1.2/294

Suspension 125 mg/5 ml: M/20.1.2/540

Suspension 250 mg/5 ml: M/20.1.2/541

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Litha Pharma (Pty) Ltd

106 16th Road

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1686

DATE OF PUBLICATION OF THE PACKAGE INSERT:

19 April 1991