SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Of

VISLAGYL SUSPENSION

1. NAME OF THE MEDICINAL PRODUCT

Vislagyl Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Metronidazole 200mg

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Metronidazole suspension is indicated for the treatment of infections caused by anaerobic bacteria and certain protozoa in paediatric patients. These include:

- Bacterial infections, such as those caused by Clostridium difficile.
- Protozoal infections, including giardiasis and amebiasis.

4.2 Posology and method of administration

Posology

Prophylaxis: against anaerobic infection- chiefly in the context of abdominal (especially colorectal) and gynaecological surgery.

Dosage:

Children < 12 years: 20 – 30mg/kg as a single dose given 1 – 2 hours before surgery.

Newborns with a gestation age <40 weeks: 10mg/kg body weight as a single dose before operation.

Treatment of established anaerobic infection:

Children > 8 weeks to 12 years of age: The usual daily dose is 20 – 30mg/kg/day as a single dose or divided into 7.5mg/kg every 8 hours. The daily dose may be increased to 40mg/kg, depending on the severity of the infection. Duration of treatment is usually 7 days.

Children < 8 weeks of age: 15mg/kg as a single dose daily or divided into 7.5mg/kg every 12 hours.

Eradication of Helicobacter pylori in paediatric patients:

As a part of combination therapy, 20mg/kg/day not to exceed 500mg twice daily for 7 – 14 days. Official guidelines should be consulted before initiating therapy.

4.3 Contraindications

- Hypersensitivity to metronidazole or any of the excipients.
- Severe liver impairment.

- Active neurological disorders, including seizures

4.4 Special warnings and precautions for use

- Monitor liver function in patients with liver disease.
- Caution in patients with a history of blood dyscrasias.
- Discontinue use if neurological symptoms occur.
- Avoid alcohol during treatment and for 48 hours after completion due to potential disulfiram-like reactions

4.5 Interaction with other medicinal products and other forms of interaction

Metronidazole may interact with:

- Alcohol, leading to severe reactions.
- Anticoagulants, increasing the risk of bleeding.
- Lithium, potentially increasing lithium levels.
- Other medications that affect liver enzymes

4.6 Pregnancy and Lactation

Pregnancy

Metronidazole is contraindicated during pregnancy.

Breast-feeding

Metronidazole is excreted in breast milk. Caution is advised when administering to nursing mothers, and it may be necessary to discontinue breastfeeding during treatment.

4.7 Effects on ability to drive and use machines

Metronidazole may cause dizziness, drowsiness, or confusion. Patients should be advised not to drive or operate machinery if they experience these effects.

4.8 Undesirable effects

Common side effects include:

- Gastrointestinal disturbances (nausea, vomiting, diarrhea).
- Neurological effects (headache, dizziness, seizures).
- Allergic reactions (rash, pruritus).
- Serious adverse effects may include severe skin reactions and liver toxicity

4.9 Overdose

Symptoms

Single oral doses of metronidazole, up to 12g have been reported in suicide attempts and

accidental overdoses. Symptoms were limited to vomiting, ataxia and slight disorientation.

Management

There is no specific antidote for metronidazole overdosage. In cases of suspected massive overdose, symptomatic and supportive treatment should be instituted

5.0 Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterial and antiprotozoal agent.

ATC code: P01AB01

Mechanism of Action

The selective action of this compound against anaerobes and anoxic and hypoxic cells is due to the mode of action. The nitro group of metronidazole acts as electron acceptor and is thus reduced to a chemically reactive drug form. This produces biochemical lesions in the cells, thus causing death. The major site of action is believed to be DNA, where it causes loss of the helical structure and inhibits synthesis.

5.2 Pharmacokinetic properties

It is readily absorbed from the gastro-intestinal tract and widely distributed in body tissues. Half life in plasma is about 8-10 hours. About 10% is bound to plasma proteins.

It penetrates well into body tissues and fluids, including vaginal secretions, seminal fluid, saliva and breast milk. Therapeutic concentrations are also achieved in cerebrospinal fluid.

Unchanged metronidazole and several metabolites are excreted in the urine, the liver is the main site of metabolism and the major metabolites are as a result of side chain oxidation, forming glucuronides.

5.3 Preclinical safety data

In animal studies, metronidazole has shown evidence of teratogenic effects at high doses. Long-term studies indicate potential for carcinogenicity with prolonged exposure.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Propyl Paraben
- C.M.C
- Methyl Paraben
- Citric acid (Monohydrate)
- Ethanol
- Raspberry flavor
- Sucrose

- Glycerine
- Tween 20
- Sodium Citrate
- Tetrazine yellow

6.2 Incompatibilities

None known

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30 °C. Keep away from sunlight.

Keep out of reach of children.

6.5 Nature and contents of container

60ml Amber bottle with aluminium screw cap.

6.6 Special precautions for disposal and other handling

No special requirements apart from NAFDAC guidelines

7.0 APPLICANT/MANUFACTURER

DE-SHALOM PHARM LAB NIG. LTD.

Km 4, Iloko-Ijesa Road, Ilesa, Osun-State, Nigeria.

Phone:08034088756

Email: deshalompharm@gmail.com