Summary of Product Characteristics of Pharmaceutical products

1. Name of the medicinal product

Natsidine Syrup (Paromomycin Oral Syrup 125mg/5ml)

2. Qualitative and quantitative composition

Each 5.0ml contains:
Paromomycin Sulfate
Eq.to paromomycin..... 125mg
For a full list of excipients, see Section 6.1.

3. Pharmaceutical form

Syrup

4. Clinical particulars

4.1 Therapeutic indications

Paromomycin is an aminoglycoside antibiotic that has been administered by mouth as sulphate in the treatment of intestinal protozoal infection including amoebiasis, cryptosporidiosis, and giardiasis.

It has also been tried parenterally for visceral and topically for cutaneous leishmaniasis. Paromomycin Sulfate may also be used for the treatment of tapeworm infection, but it is not the treatment of choice.

Similarly, Paromomycin Sulfate has been used in the suppression of intestinal flora both preoperatively and in the management of hepatic encephalopathy.

4.2 Posology and method of administration Dosage:

Amoebiasis, Giardiasis (Lambliasis) and Balantidiasis:

Adult and Children:25-30mg/kg/day daily in 3 divided dose for 5-10days.

Cryptosporidiosis:

Adult: 25-30mg/kg/day daily in 3 divided dose for 5-10days**.**

Gastro-enterities and enterocolitis due to mixed flora ,salmonellosis and shigellosis:

Adult:500mg twice a day for 5-7days.
Children**:**30/mg/day in two divided dose for 5-7days

Prophylactic sterilization in gastro-intestinal surgery:

Adult:2g daily for 3days.
Children:50mg/kg/day for 3days.

Prophylactic treatment of hepatic coma:

Adult:2 g for 6days.

Children:50mg/kg/day for 6days

Natsidine is administered orally, with or after meals, in 2-4 divided doses. The physician can also adjust the dosage and duration of treatment according to the severity and duration of the diseases.

4.3 Contraindications

Paromomycin sulfate is contraindicated in **individuals with a history of previous hypersensitivity reactions to** it. It is also contraindicated in intestinal obstruction.

4.4 Special warnings and precautions for use

Paromomycin Sulfate is contraindicated for intestinal disinfection when an obstruction is present and in patients with a known history of allergy to aminoglycosides. It should be used with great care in patients with kidney or liver disease or neuromuscular disorders and those with impaired hearing.

4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions:

- Absorption following oral administration may be sufficient to produce interactions with other drugs administered systemically.
- Paromomycin Sulfate taken by mouth, may impair the absorption of other drugs including Phenoxymethylpenicillin, Digoxin, Methotrexate, and some vitamins; the efficacy of oral contraceptives might be reduced. Paromomycin Sulfate may enhance the effects of Acarbose.

4.6 Pregnancy and Brest Feeding:

The medication is poorly absorbed. The effect it may have on the baby is still unknown.

There is limited data regarding the safety of taking paromomycin while breastfeeding but because the drug is poorly absorbed minimal amounts of drug will be secreted in breastmilk

4.7 Effects on ability to drive and use machines

Temporary blurred vision may occur which may affect the ability to drive or using machine.

4.8 Undesirable effects

The include anorexia, nausea,vomitting,epigastric burning and pain ,increase gastro-intestinal motility,abdominal cramp,diarrhoea,and puritua ani.Paromomycin has also been reported to cause Hypocholesterolemic and malabsorption effects.Malabsorption of xylose,sucrose and abnormal fat metabolism have been demonstrated.

Paromomycin may also cause steatorrhea by prescription of bile salt.Other adverse effect reported following oral administration of Paromomycin include rash,headache,vertigo,eosinophilia,exanthema,and unexplained hematuria.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the Pharmacy and Poisons Board (PPB) through the Pharmacovigilance Electronic Reporting System (PvERS) at https://pv.pharmacyboardkenya.org/ or by using the approved PPB ADR reporting forms

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Paromomycin Sulfate is active against various protozoa including: Leishmania spp; Entamoeba histolytica, and Cryptosporidium spp. In addition, it has an antibacterial spectrum similar to that of neomycin. It is active against many strains of gram-negative bacteria including species of Brucella, Calymmatobacterium, Campylobacter, Citrobacter, Escherichia, Enterobacter, Klebsiella, proteus, Serratia Vibrio and Yersinia. Paromomycin Sulfate has been reported to be active against Mycobacterium tuberculosis but lacks activity against Pseudomonas aeruginosa.

5.2 Pharmacokinetic properties

Paromomycin Sulfate is poorly absorbed from the gastrointestinal tract and most of the dose is eliminated unchanged in the faeces.

5.3 Pre-clinical Safety:

This is an open label, Promomycin Phase III, randomized, controlled, parallel arm multicentre non-inferiority clinical trial to compare the efficacy and safety of two combination regimens of Paromomycin with the standard SSG-PM for the treatment of primary adult and children VL patients in Eastern Africa.

6. Pharmaceutical Particulars:

6.1 List of Excipients:

No.	Name of the

	Excipients
1	Sugar
2	Sorbitol 70%
3	Sodium methyl Paraben
4	Sodium Propyl Paraben
5	Citric Acid
6	Ess. Mixed fruit Liquid
7	Sodium Benzoate
8	Sodium Saccharin

9	Colour: Tartrazine Yellow
10	Purified Water

6.2 Incompatibilities: Nil.

6.3 Shelf Life: 36 months.

6.4 Special Precautions for storage: Store in a dry place below 25℃. Protect from light.

6.5 Nature and contents of container:
60ml syrup in PET amber bottle affixed with coded label which has batch number, manufacturing date and expiry dates, packed in unit box with insert.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorization holder and manufacturing site address Marketing authorization holder
Name: National Pharmacy Ltd,
Address: P.O. Box 17843-00500, Nairobi
Country: Kenya

Manufacturing site
Name: Zain Pharma limited
Address: Plot No: 209/13741, Colchester Park, Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice And Lovely House, P.O. Box: 100167-00101, Nairobi, Kenya Country: India

8. Marketing Authorization Number
H2022/CTD9337/21299

9. Date of first Authorization /renewal of the authorization
29/05/2023

10. Date of revision of text
15/09/2023