Summary Product Characteristics (SPC)

1. Name of the medicinal product
GASTORAL SYRUP

2. Qualitative and quantitative composition
Each 5mL contains: Aminosidine Sulphate Equivalent to Aminosidine 125mg

3. Pharmaceutical form
Syrup

4. Clinical particulars

4.1 Therapeutic indications
Aminosidine (gastroral) 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. Aminosidine may also be used for the treatment of tapeworm infection, but it is not the treatment of choice. Similarly to Neomycin, Aminosidine 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:

Prophylactic treatment of hepatic coma:

Adult: 2g daily for 6 days
Children: 50mg/kg/day for 6 days
Aminosidine Sulphate is administered orally, with or after meals, in 2-4 divided doses. The physician can also adjust the dosages and duration of treatment according to the severity and duration of the diseases.

DOSAGE AND ADMINISTRATION:

Diagnosis	Dosage	Duration of Therapy
Amoebiasis, Giardiasis (Lambliasis) and Balantidiasis	**Adults:** 500mg twice a day **Children:** 30mg/kg/day in two divided doses.	5-7 days 5-7 days
Cryptosporidiosis	**Adults:** 500mg four times a day	14 days
Gastro-enteritis and enterocolitis due to mixed flora, salmonellosis and shigellosis	**Adults**: 500mg twice a day. **Children**: 30mg/kg/day in two divided doses.	5-7 days 5-7 days
Prophylactic sterilization in gastro-intestinal surgery.	**Adult**: 2 kg daily **Children**: 50mg/kg/day	3 days 3 days

4.3 Contraindications:
Aminosidine 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:
Aminosidine 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:
Absorption following oral administration may be sufficient to produce interactions with other drugs administered systemically. Aminosidine 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. Aminosidine may enhance the effects of Acarbose

4.6 Fertility, Pregnancy and lactation:
Aminosidine has not been formally assigned to a pregnancy category by the FDA. Aminosidine is poorly absorbed from the gastrointestinal tract; therefore, little drug would be available to reach the fetus. There are no data linking the use of Aminosidine to congenital malformations or fetal toxicity, although there are no controlled data in human pregnancy. In pregnant patients with symptomatic protozoan or tapeworm infections, Paromomycin may be a therapeutic option. Aminosidine should only be given during pregnancy when there are no alternatives and benefit outweighs the risk.
In one report, two women were treated with Aminosidine for 10 days for symptomatic Giardia infections during the 10^{th} and 20^{th} week of pregnancy. No congenital malformations or fetal toxicity were reported.
Aminosidine is poorly absorbed from the gastrointestinal tract; therefore, any excretion into breast milk is expected to be minimal.

4.7 Effects on ability to drive and use machines
Not demonstrated

4.8 Undesirable effects:
Aminosidine Sulphate particularly when administered in large doses may cause anorexia, nausea, vomiting, abdominal cramps, epigastric burning and diarrhoea. Nephrotoxicity and ototoxicity have very rarely been reported.

4.9 Overdose
Symptoms of Aminosidine sulfate overdose are not known.

5. Pharmacological properties

5.1 Pharmacodynamic properties.
Aminosidine Sulphate 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. Aminosidine has been reported to be active against *Mycobacterium tuberculosis* but lacks activity against *Pseudomonas aeruginosa*.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Preclinical data few preclinical data on the efficacy and safety of combination therapies for visceral leishmaniasis are available. An early study looked at interactions between sodium stibogluconate and Paromomycin. Whereas a marked potentiation was reported against L donovani in vitro, a less-pronounced, additive effect of the antimonial drug was noted in mice. Another study specifically focused on interactions in efficacy between miltefosine and sodium stibogluconate, amphotericin B, Paromomycin, and sitamaquine (an oral aminoquinoline). In vivo, the highest enhancement of miltefosine activity was seen with amphotericin B, which preceded Paromomycin. No activity enhancement was seen with miltefosine combined with sodium stibogluconate. Whereas the combination of miltefosine and amphotericin B could theoretically have some advantages over the other combinations, its clinical relevance remains unknown. More recent findings have also shown a synergistic interaction between amphotericin B and Paromomycin. Preclinical studies on several drug combinations have been done, with no major safety concerns identified (R Don, Drugs for Neglected Diseases initiative, personal communication, Jan 15, 2010).

6. Pharmaceutical particulars

6.1 List of excipients

Sodium citrate
Sorbitol 70% solution
Glycerin
Erythrosine soluble colour
Raspberry essence liquid
Sodium Methyl paraben
Sodium Propyl paraben
Sodium Hydroxide
Purified Water

6.2 Incompatibilities:

None known

6.3 Shelf life:

24 months

6.4 Special precautions for storage:

Store in a dry place at a temperature not exceeding 30°C
Protect from light

Keep all medicines out of reach of children
Replace cap securely

6.5 Nature and contents of the container:
Amber PET bottles of 60mL and 100 mL

6.6 Special precautions for disposal:
No special requirements

7. Registrant:
Company name: LABORATORY & ALLIED LTD
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P.O BOX 42875, CODE 00100 NAIROBI
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