

# Daboral®



25400

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## Aminosidine Sulphate Antiprotozoal

DABORAL® TABLETS 250MG  
DABORAL® SYRUP 125MG/5ML

### PRESENTATION:

**Daboral® Tablets 250mg:** White to off white, circular flat bevelled edge tablet with a breakline on one side and plain on the other side. Each tablet contains: Aminosidine Sulphate equivalent to Aminosidine Base 250mg.

**Daboral® Syrup 125mg/5mL:** Light to golden yellow solution free from visible evidence of contamination with pleasant taste. Each 5mL contains: Aminosidine Sulphate equivalent to Aminosidine Base 125mg.

### CLINICAL PHARMACOLOGY:

Aminosidine Sulphate (paromomycin) is an aminoglycoside antibiotic. Aminosidine has a broad spectrum of activity, including activity against protozoa especially *Entamoeba histolytica*, *bacteria* and *cestodes*. The drug is believed to act against both the trophozoite and encysted forms of *Entamoeba*. Aminosidine has an antibacterial spectrum similar to that of neomycin. Aminosidine is active against some gram-positive bacteria (e.g. some strains of *Staphylococcus*) and many gram-negative aerobic bacteria, but generally is inactive against *Pseudomonas aeruginosa* and anaerobic bacteria. Aminosidine also has some activity against *Mycobacterium tuberculosis*. Aminosidine has been shown to be active against certain cestodes (tapeworms) pathogenic to humans including *Diphyllobothrium latum* (fish tapeworm), *Taenia saginata* (beef tapeworm), and *T.solium* (pork tapeworm).

### Pharmacokinetics:

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

### USES:

Daboral® is used in the treatment of intestinal protozoal infections, including amoebiasis, cryptosporidiosis, and giardiasis. It has been used in the treatment of tapeworm infection. Also in the suppression of intestinal flora both pre-operatively and in the management of hepatic encephalopathy.

### DOSAGE AND ADMINISTRATION:

#### Amoebiasis, Giardiasis (Lambliasis) and Balantidiasis:

**Adults and Children:** 25-30/kg/day daily in 3 divided doses for 5-10 days.

#### Cryptosporidiosis:

**Adults:** 25-30/kg/day daily in 3 divided doses for 5-10 days.

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

**Adults:** 500mg twice a day for 5-7 days.

**Children:** 30mg/kg/day in two divided doses for 5-7 days.

#### Prophylactic sterilization in gastro-intestinal surgery:

**Adults:** 2g daily for 3 days.

**Children:** 50mg/kg/day for 3 days.

#### Prophylactic treatment of hepatic coma:

**Adults:** 2g daily for 6 days.

**Children:** 50mg/kg/day for 6 days

Daboral® 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.

### CONTRA-INDICATIONS AND WARNINGS:

#### Precautions:

The use of Aminosidine may result in the overgrowth of nonsusceptible organisms, especially *Candida*, and patients should be carefully monitored for the development of new infections caused by nonsusceptible organisms. Secondary *Staphylococcus*

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enterocolitis may occur. Aminosidine should be administered with caution to patients with ulcerative intestinal lesions to avoid renal toxicity through inadvertent absorption of the drug. High doses or prolonged therapy with Aminosidine should be avoided. Since Aminosidine is only active against intestinal protozoa, the drug should not be used in the treatment of extra intestinal amoebiasis. Aminosidine is contraindicated in patients with intestinal obstruction and in patients with a known hypersensitivity to the drug.

## **Adverse Effects:**

They include anorexia, nausea, vomiting, epigastric burning and pain, increased gastro-intestinal motility, abdominal cramps, diarrhoea, and pruritus ani. Aminosidine has also been reported to cause hypocholesterolemic and malabsorptive effects. Malabsorption of xylose, sucrose and abnormal fat metabolism have been demonstrated. Aminosidine may also cause steatorrhea by precipitation of bile salts. Other adverse effects reported following oral administration of Aminosidine include rash, headache, vertigo, eosinophilia, exanthema, and unexplained haematuria.

## **Interactions:**

Aminosidine has been reported to impair the absorption of other drugs including phenoxymethylpenicillin, digoxin and methotrexate; the efficacy of oral contraceptives might be reduced. The effects of acarbose may be enhanced.

## **Pregnancy and Lactation:**

Due to limited data on the safety of aminosidine during pregnancy and lactation cannot be established. The drug should be taken on physician's advice.

## **PHARMACEUTICAL PRECAUTIONS:**

Store in a dry place below 25°C. Protect from light. Keep all medicines out of the reach of children.

## **LEGAL CATEGORY:**

Prescription Only Medicine (POM)

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