

Minodine Aminosidine Syrup / Tablets

Composition:

Each tablet contains Aminosidine Sulphate USP equivalent to Aminosidine base 250 mg.

List of Excipients: Lactose, Maize Starch, Povidone, Aerosil, Magnesium Sterate and Talc.

Each 5ml of the syrup contains Aminosidine Sulphate USP equivalent to Aminosidine base 250mg.

List of Excipients: Sodium CMC, Sodium Saccharin, Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Benzoate, Ponceau Colour, Pineapple flavor and Sodium Hydroxide.

Pharmacology:

Aminosidine is a bactericidal aminoglycoside antibiotic that appears to inhibit protein synthesis in susceptible bacteria at the 30S segment of the ribosome. It is considered a luminal or contact amebicide since it acts principally in the intestinal lumen. Aminosidine is a direct-acting amebicide and is effective either in the presence or absence of bacteria. Aminosidine sulfate has a broad spectrum of activity, including activity against protozoa, bacteria, and cestodes.

It is active against protozoa, especially *Entamoeba histolytica*. The drug is believed to act against both the trophozoite and encysted forms of *Entamoeba*.

Limited in vitro studies indicate that aminosidine concentrations of 5mcg/ml may be amebistatic and concentrations of 10mcg/ml may be amebicidal.

Pharmacokinetics:

Aminosidine sulfate is poorly absorbed from the GI tract, and most of an oral dose is excreted unchanged in feces. Impaired GI motility, or lesions or ulcerations of the intestine may facilitate absorption of the drug. Accumulation can occur in patients with impaired renal function. Almost 100% of an oral dose is eliminated unchanged in feces; any absorbed drug is slowly excreted in urine.

Therapeutic indications:

Amebiasis: Aminosidine sulfate is used as a luminal amebicide in the treatment of amebiasis caused by *Entamoeba histolytica*. It is used alone for the treatment of asymptomatic intestinal amebiasis and is considered a drug of choice for the treatment of asymptomatic cyst passers, especially in children and pregnant women.

Balantidiasis: Aminosidine has been used with some success for the treatment of balantidiasis caused by *Balantidium coli*.

Cestode (Tapeworm) Infections: Aminosidine has been used effectively for the treatment of cestodiasis (tapeworm infection) caused by certain cestodes pathogenic to humans including *Diphyllobothrium latum* (fish tapeworm), *Dipylidium caninum* (dog and cat tapeworm), *Hymenolepis nana* (dwarf tapeworm), *Taenia saginata* (beef tapeworm), and *Taenia solium* (pork tapeworm).

Cryptosporidiosis: Aminosidine reportedly has been beneficial in the treatment of cryptosporidiosis caused by *Cryptosporidium parvum* in some patients with human immunodeficiency virus (HIV) infection.

Dientamoeba fragilis Infections: Aminosidine is considered a drug of choice for the treatment of infections caused by *Dientamoeba fragilis*.

Hepatic Encephalopathy: Aminosidine has been used in the management of hepatic coma as an adjunct to protein restriction and supportive therapy to inhibit nitrogen-forming bacteria of the GI tract.

Other Uses: Aminosidine has been used for the treatment of acute bacillary dysentery, carrier states of Shigella, and gastroenteritis caused by *Escherichia coli*.

Dosage and Administration:

Aminosidine sulfate is administered orally with a meal. When aminosidine is used in the treatment of mild to moderate or severe intestinal amebiasis or extra intestinal amebiasis (including hepatic abscess), *Dientamoeba fragilis* infections, cryptosporidiosis in children, adolescents, or adults with human immunodeficiency virus (HIV) infection and Giardiasis infections the usual dosage in adults and children is 25-35 mg/kg daily (250mg or 500mg 3 times daily), administered in 3 divided doses, for 5-10 days (usually 7 days).

For the treatment of cestodiasis caused by *Hymenolepis nana*, a dosage of 45 mg/kg daily, given as a single daily dose for 5-7 days is used in adults and children. Multiple-day therapy is necessary in *Hymenolepis nana* infections, since the drug is not as effective against the larval stage of the worms as it is against adult worms.

In hepatic Encephalopathy as an adjunct in the management of hepatic coma, adults can receive aminosidine in a dosage of 4g daily in divided doses given for 5-6 days.

Contraindications and precautions:

Aminosidine is contraindicated in patients with known hypersensitivity to the drug. It is contraindicated in patients with intestinal obstruction.

The use of aminosidine may result in the overgrowth of nonsusceptible organisms, including fungi, and patients should be carefully monitored for the development of new infections caused by non-susceptible organisms. Secondary Staphylococcus enterocolitis may occur. Like other aminoglycosides, aminosidine has potential nephrotoxic, ototoxic, and probably neuromuscular blocking effects. Oral aminosidine should be administered with caution to patients with ulcerative intestinal lesions to avoid renal toxicity through inadvertent absorption of the drug. Since aminosidine is only active against intestinal protozoa, the drug should not be used alone in the treatment of extraintestinal amebiasis.

Use during Pregnancy and Lactation

Aminosidine is poorly absorbed when given orally. Because it does not reach the maternal serum, it would not be expected to distribute into human milk or adversely affect the Foetus. However use with caution.

Adverse reactions:

Adverse GI effects reported with oral aminosidine include anorexia, nausea, vomiting, epigastric burning and pain, increased GI motility, abdominal cramps, diarrhea, and pruritus ani. Aminosidine has also been reported to cause hypocholesterolemic and malabsorptive effects similar to those of neomycin.

Malabsorptions of xylose and sucrose, and abnormal fat metabolism have been demonstrated. Aminosidine may also cause steatorrhea by precipitation of bile salts. Other adverse effects which have occasionally been reported with oral aminosidine include rash, headache, vertigo, eosinophilia, exanthema, and unexplained hematuria.

Drug Interactions

Aminosidine causes decreased effect of digoxin, vitamin A, and methotrexate; increased effect of oral anticoagulants, neuromuscular blockers, and polypeptide antibiotics.

Overdose Management

Overdose causes nausea, vomiting, diarrhea. Supportive and symptomatic treatment to be given.

Presentation:

Syrup: 60ml in amber coloured glass bottles.

Tablets: Blister pack of 2 x 10's and 2 x 6's in a unit box.

Storage:

Store in a dry place, below 30°C. Protect from light.

Keep all medicines out of reach of children.

Manufactured By:



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