

# NIAZID

## Nitazoxanide

500 mg Tablet  
100 mg/5 ml PFS

### DESCRIPTION

NIAZID (Nitazoxanide) is a novel broad-spectrum antiprotozoal and antiparasitic agent. The antiprotozoal & antiparasitic activity of Nitazoxanide is believed to be due to interference with the Pyruvate-Ferredoxin Oxidoreductase (PFOR) enzyme dependent electron transfer reaction, which is essential for anaerobic energy metabolism of the parasites. Nitazoxanide are readily reduced by PFOR enzymes from the parasites by transfer of electrons; this reduced form of Nitazoxanide deprives parasite of their energy and eradicate them.

Nitazoxanide is well absorbed from GIT and following oral administration Nitazoxanide is rapidly hydrolysed to an active metabolite, tizoxanide. Nitazoxanide is highly bound to plasma protein (>99.9%). When Nitazoxanide is administered with food, the AUC in plasma is increased by about 45-50% and the C<sub>max</sub> is increased by ≤10%.

### COMPOSITION

**NIAZID Tablet** Each tablet contains Nitazoxanide INN 500 mg.

**NIAZID 30 ml PFS** When reconstituted each 5 ml suspension contains Nitazoxanide INN 100 mg.

**NIAZID 60 ml PFS** When reconstituted each 5 ml suspension contains Nitazoxanide INN 100 mg.

### INDICATION

NIAZID (Nitazoxanide) is active against various strains of **Protozoa** including *Giardia lamblia*/*Giardia intestinalis*, *Trichomonas vaginalis*, *Entamoeba histolytica*, *Cryptosporidium* and **Helminths** including Nematodes-*Enterobius vermicularis*, *Ascaris lumbricoides* (round worm), *Trichuris trichura* (whip worm), *Ancylostoma duodenale* (hook worm), *Strongyloides stercoralis* (round worm). Cestodes-*Taenia saginata* (tape worm), *Hymenolepis nana* (dwarf tape worm). Trematodes-*Fasciola hepaticum*. In addition, the compound is reported to possess activity against the **bacteria** *Helicobacter pylori* and anaerobic bacterial infections : *Clostridium difficile*, *Bacteroides fragilis*

NIAZID (Nitazoxanide) is indicated in the following infections :

- Protozoal diarrhoea : Giardiasis, Cryptosporidiosis, Amoebiasis
- Trichomoniasis
- Helminth infections
- *Helicobacter pylori* infection
- Anaerobic bacterial infections : *Clostridium difficile*, *Bacteroides fragilis*

### DOSAGE AND ADMINISTRATION

Infection	Age	Dose	Duration
Giardiasis, Cryptosporidiosis, Amebiasis, helminth, Trichomoniasis	1-3 years	100 mg (5 ml Niazid PFS) twice daily with food	3 days
	4-11 years	200 mg (10 ml Niazid PFS) twice daily with food	
	≥12 years	500 mg (1 Niazid Tablet) twice daily with food	

In *H. pylori* eradication : 1 gm (2 Niazid Tablet) twice daily with Omeprazole (Aspra-20) for 7 days

### CONTRAINDICATION

NIAZID is contraindicated in known hypersensitivity to Nitazoxanide.

### PRECAUTION

NIAZID (Nitazoxanide) should be used with caution in hepatic, renal and biliary diseases.

### IN PREGNANCY AND LACTATION

**Pregnancy** : Pregnancy category B. This drug should be used during pregnancy only if clearly needed.

**Lactation** : It is not known whether Nitazoxanide is excreted in human milk. But caution should be exercised when Nitazoxanide is administered to a nursing woman.

### SIDE EFFECT

NIAZID (Nitazoxanide) is generally well tolerated. However, abdominal pain, vomiting, headache, anorexia, flatulence, appetite increase, malaise, sweating and dizziness have been reported rarely.

### DRUG INTERACTION

Caution should be used when administering Nitazoxanide concurrently with other highly plasma protein-bound drugs of narrow therapeutic indices (e.g. warfarin), as competition for binding sites may occur.

### DIRECTION FOR RECONSTITUTION OF NIAZID SUSPENSION

Shake the bottle until whole powder flows freely. Then add boiled & cool water, 20 ml (4 teaspoonfull) for NIAZID 30 ml PFS and 40 ml (8 teaspoonfull) for NIAZID 60 ml PFS and shake well to mix powder. For better mixing add total water in two portion and shake well each time.

**Note** : After reconstitution keep the bottle tightly closed and shake the bottle well before each use. Reconstituted suspension must be used within 7 days if kept at room temperature or within 10 days when stored in a refrigerator.

### STORAGE

Store in cool dry place and away from light. Keep out of the reach of children.

### HOW SUPPLIED

**NIAZID Tablet** Box containing 7 x 4's tablet in Alu-Alu strips.

**NIAZID 30 ml PFS** Bottle containing powder to make 30 ml Suspension when reconstituted.

**NIAZID 60 ml PFS** Bottle containing powder to make 60 ml Suspension when reconstituted.



Manufactured by  
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