

# Nitoxin

Nitazoxanide INN

## Composition:

**Nitoxin Tablet:** Each film coated tablet contains Nitazoxanide INN 500 mg.

**Nitoxin Powder for Suspension:** After reconstitution each 5 ml suspension contains Nitazoxanide INN 100 mg.

## Pharmacology:

The antiprotozoal activity of Nitazoxanide is believed to be due to interference with the pyruvate ferredoxin oxidoreductase (PFOR) enzyme-dependent electron transfer reaction which is essential to anaerobic energy metabolism. Nitazoxanide and its metabolite, tizoxanide are readily reduced by PFOR enzymes from the parasites by transfer of electrons. This reduced form of Nitazoxanide deprives parasite of their energy and eradicates them.

## Indications:

Nitoxin (patients 1 year of age and older) is indicated for the treatment of diarrhoea caused by *Giardia lamblia* or *Cryptosporidium parvum*. It is also effective in protozoan infections (Amoebiasis and Trichomoniasis) and helminth infections.

## Dosage & Administration:

Age	Dosage	Duration
1-3 years	5 ml Suspension (100 mg Nitazoxanide) every 12 hours with food	3 days.
4-11 years	10 ml Suspension (200 mg Nitazoxanide) every 12 hours with food	
≥12 years	1 Tablet or 25 ml Suspension (500 mg Nitazoxanide) every 12 hours with food	

## Side-effects:

The most common side effects associated with Nitazoxanide are abdominal pain and diarrhoea. Nausea and vomiting, flatulence, and increased appetite have also been reported. Headache may occur. Other reported side effects include fever, malaise, pruritus, sweating, dizziness and rhinitis.

## Contraindications:

Nitazoxanide is contraindicated in patients with a prior hypersensitivity to Nitazoxanide or any other ingredient in the formulations.

## Precautions:

Nitazoxanide must be administered with caution to patients with hepatic and biliary disease, to patients with renal disease and to patients with combined renal and hepatic diseases.

## Use in pregnancy:

Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. So this drug should be used during pregnancy only if clearly needed.

## Use in nursing mothers:

It is not known whether Nitazoxanide is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nitazoxanide is administered to a nursing woman.

## Paediatric use:

Safety and effectiveness of Nitazoxanide in paediatric patients less than one year of age have not been studied.

## Drug Interactions:

Nitazoxanide is highly bound to plasma protein (>99.9%). Therefore, caution should be used when administering Nitazoxanide concurrently with other highly plasma protein-bound drugs with narrow therapeutic index.

## Storage:

Store the tablets, powder for suspension and the reconstituted oral suspension in below 30°C, keep in dry place & protect from light. The container should be kept tightly closed and the suspension should be shaken well before each use. The suspension may be stored for 7 days, after which any unused portion must be discarded.

## Packing:

**Nitoxin Tablet:** Box containing 5x6's tablets in Alu-Alu blister pack.

**Nitoxin Powder for Suspension:** Bottle containing dry powder for reconstitution of 30 ml Suspension.

Manufactured by:



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