Nizonid

Nitazoxanide

COMPOSITION:

Nizonid Tablet: Each tablet contains Nitazoxanide INN 500 mg.
Nizonid PFS: Each 5 ml suspension contains Nitazoxanide INN 100 mg.

PHARMACOLOGY:

Pharmacodynamics

The anti-protozoal 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.

It has also been shown to have activity against influenza A virus in vitro.The mechanism appears to be by selectively blocking the maturation of the viral hemagglutinin at a stage preceding resistance to endoglycosidase H digestion. This impairs hemagglutinin intracellular trafficking and insertion of the protein into the host plasma membrane.

Pharmacokinetics

Following oral administration, Nitazoxanide is rapidly hydrolyzed to the pharmacologically active metabolite, tizoxanide, which is 99% protein bound.Tizoxanide is then glucuronide conjugated into the active metabolite, tizoxanide glucuronide.Peak plasma concentrations of the metabolites tizoxanide and tizoxanide glucuronide are observed 1–4 hours after oral administration of Nitazoxanide, whereas Nitazoxanide itself is not detected in blood plasma.

Roughly 2⁄3 of an oral dose of Nitazoxanide is excreted as its metabolites in feces, while the remainder of the dose excreted in urine.Tizoxanide is excreted in the urine, bile and feces.Tizoxanide glucuronide is excreted in urine and bile.

INDICATION:

Nizonid is used specifically for diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* and Amebiasis and helminth infections.

DOSAGE AND ADMINISTRATION:

Age 1 - 3 years: 5 ml (100 mg) twice daily for 3 days,
Age 4 - 11 years: 10 ml (200 mg) twice daily for 3 days,
Age >12 years : 25 ml or 1 tablet (500 mg) twice daily for 3 days.

CONTRAINDICATION:

Known hypersensitivity to Nitazoxanide or any other ingredient in the formulations.

WARNING & PRECAUTION:

Nitazoxanide should be administered with caution to patients with hepatic, renal and biliary disease.

USE IN PREGNANCY AND LACTATION:

Pregnancy Category B.This drug should be used during pregnancy only if clearly needed.
Nursing Mothers: It is not known whether Nitazoxanide is excreted in human milk. As many drugs are excreted in human milk, caution should be exercised when Nitazoxanide is administered to a nursing woman.

SIDE EFFECT:

Nitazoxanide is generally well tolerated. In placebo-controlled clinical trials, the incidence of side-effects did not differ significantly from those of the placebo. None of the 613 pediatric patients discontinued therapy because of side-effects. In controlled and uncontrolled clinical studies pediatric patients who received Nitazoxanide the side-effects were abdominal pain, vomiting and headache. These were typically mild and transient in nature. Side-effects occurring in less than 1% of patients are anorexia, flatulence, appetite increase, malaise, sweating and dizziness.

DRUG INTERACTION:

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 window.

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OVERDOSAGE:

Information on Nitazoxanide overdosage is not available. Single oral doses of up to 4000 mg Nitazoxanide have been administered to healthy adult volunteers without significant adverse effects.

STORAGE:

Store in a cool and dry place (below 30°C), protected from light and moisture. Keep out of reach of children.

PACKING:

Nizonid Tablet: Each box contains 3x4 tablets in Alu-Alu blister.
Nizonid PFS: Each bottle contains dry ingredient to make 30 ml suspension with measuring spoon.

Manufactured By:

MEDICON

MEDICON Pharmaceuticals Ltd
Mirpur, Dhaka, Bangladesh