

Nanazoxid 500 mg tablet

Nitazoxanide 500mg

Film-coated Tablets

Composition:

Each tablet contains:

Active Ingredients:

Nitazoxanide 500mg.

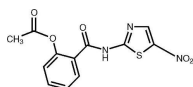
Inactive Ingredients:

Starch, sucrose, sodium starch glycolate, talc, magnesium stearate, poly vinyl alcohol, HPMC titanium dioxide.

Description:

Nanazoxid 500mg tablets contains the active ingredient nitazoxanide; a synthetic antiprotozoal agent for oral administration. Chemically, nitazoxanide is 2-acetyloxy-*N*-(5-nitro-2-thiazolyl) benzamide.

The structural formula is:



Clinical Pharmacology:

Absorption: Following oral administration of **Nanazoxid 500mg** tablets, maximum plasma concentrations of the active metabolites tizoxanide and tizoxanide glucuronide are observed within 1-4 hours. The parent nitazoxanide is not detected in plasma. When **Nanazoxid 500mg** tablet was administered with food, the AUC_t of tizoxanide and tizoxanide glucuronide increased almost two-folds and the C_{max} increased by almost 50%.

Distribution: In plasma, more than 99% of tizoxanide is bound to proteins.

Metabolism: Nitazoxanide is rapidly hydrolyzed to an active metabolite, tizoxanide (desacetyl-nitazoxanide). Tizoxanide then undergoes conjugation, primarily by glucuronidation.

Elimination: Tizoxanide is excreted in the urine, bile and feces, and tizoxanide glucuronide is excreted in urine and bile. Approximately two-thirds of the oral dose of nitazoxanide is excreted in the feces and one-third in the urine.

Mechanism of Action:

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.

Indications and Usage:

Nanazoxid 500mg tablets is indicated for the treatment of diarrhea caused by *giardia lamblia* or *cryptosporidium parvum*.

Dosage and Administration:

One tablet every 12 hours with food for three days.

Overdosage:

Information on nitazoxanide overdosage is not available.

Contraindications:

Nanazoxid 500gm tablets is contraindicated in patients with a prior hypersensitivity to nitazoxanide or any other ingredient in the formulation.

Adverse Reactions:

The most frequent adverse events reported were: abdominal pain, diarrhea, vomiting and headache.

Drug Interactions:

Tizoxanide 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 indices, as competition for binding sites may occur (e.g., warfarin.)

Pregnancy and Lactation:

No adequate and well-controlled studies are available in pregnant women.

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 women.

Precautions:

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

Package:

Carton box containing 1 pvdc/alum. strip; each strip has 6 tablets with an insert leaflet.

Storage:

Keep out of reach of children.

Keep at a temperature not exceeding 30°C in a dry place.

Information for Patients:

Nanazoxid 500mg tablets should be taken with food.

Produced by Medizen Pharmaceutical Industries for Utopia Pharmaceuticals