

Zoxanid[®]

Nitazoxanide INN

Composition:

Zoxanid[®] Tablet : Each film coated tablet contains Nitazoxanide INN 500 mg.

Zoxanid[®] 30 ml powder for suspension: After reconstitution each 5 ml suspension contains Nitazoxanide INN 100 mg.

Zoxanid[®] 60 ml powder for suspension: After reconstitution each 5 ml suspension contains Nitazoxanide INN 100 mg.

Description:

Nitazoxanide is a synthetic antiprotozoal agent. Nitazoxanide is well absorbed from GIT. Nitazoxanide interferes with the Pyruvate Ferredoxin Oxidoreductase (PFOR) enzyme-dependent electron transfer reaction which is important for anaerobic glucose energy metabolism. This results in cell swelling, membrane damage resulting in dysfunction of the parasite. When Nitazoxanide is administered with food, the AUC in plasma is increased almost two-fold and the C_{max} is increased by almost 50%.

Indication:

1. Diarrhea caused by *Cryptosporidium parvum* and *Giardia lamblia*.
2. Amebiasis and helminth infection.

Dosage and administration:

Indications	Age	Dose	Duration
Cryptosporidiosis, Giardiasis, Amebiasis and helminth infection	1-3 years	5 ml (1 teaspoon full) twice daily with food	3 days
	4-11 years	10 ml (2 teaspoon full) twice daily with food	
	>12 years	25 ml (5 teaspoon full) or 1 tablet twice daily with food	

Side effects:

Nitazoxanide is generally well tolerated. However abdominal pain, diarrhea, vomiting, and headache have been reported rarely.

Use in Special Group:

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

Lactation: It is not known whether Nitazoxanide is excreted in human milk. As many drugs are excreted in human milk, caution should be taken when Nitazoxanide is administered to nursing women.

Contraindications:

It is contraindicated in patients with a prior hypersensitivity to Nitazoxanide or any other ingredients in the formulation.

Warning & Precautions:

Nitazoxanide should be taken with caution to patients with hepatic or renal impairment.

Drug interactions:

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

Direction for reconstitution:

Zoxanid[®] 30 ml powder for suspension: Shake the bottle until all powder flows freely. Take 20 ml (4 teaspoonful) boiled and cool water. Add approximately one-half (2 teaspoonful) of the total amount of water required for reconstitution and shake vigorously to suspend powder. Add remainder of water and again shake vigorously until all powder is in suspension.

Zoxanid[®] 60 ml powder for suspension: Shake the bottle until all powder flows freely. Take 40 ml (8 teaspoonful) boiled and cool water. Add approximately one-half (4 teaspoonful) of the total amount of water required for reconstitution and shake vigorously to suspend powder. Add remainder of water and again shake vigorously until all powder is in suspension.

Storage:

Store in a cool and dry place, protect from light, Keep out of the reach of children.

Commercial pack:

Zoxanid[®] Tablet : Each box contains 5 x 6 tablets in blister pack.

Zoxanid[®] 30 ml powder for suspension: Bottle containing powder to make 30 ml suspension when reconstituted.

Zoxanid[®] 60 ml powder for suspension: Bottle containing powder to make 60 ml suspension when reconstituted.