

Nitasol

Nitazoxanide

Composition:

Nitasol Tablet: Each film coated tablet contains Nitazoxanide INN 500 mg. **Nitasol** 30 ml suspension: Each 5 ml reconstituted suspension contains Nitazoxanide INN 100 mg. **Nitasol** 60 ml suspension: Each 5 ml reconstituted suspension contains Nitazoxanide INN 100 mg.

Description:

Nitasol (Nitazoxanide), a synthetic antiprotozoal drug. It is well absorbed from gastrointestinal tract. It interferes with the Pyruvate Ferredoxin Oxidoreductase (PFOR) enzyme dependent electron transfer reaction which is essential to anaerobic glucose energy metabolism. This results in cell swelling, membrane damage resulting in dysfunction of the parasite.

Indication:

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

Dosage & 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. The suspension or tablet should be taken with food.

Over Dosage:

Information on Nitazoxanide over dosage is not available. Single oral doses up to 4000 mg Nitazoxanide have been administered to healthy adults without significant adverse effects.

Precautions:

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

Contraindications:

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

Pregnancy & Lactation:

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

Side Effect:

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

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.

Reconstitution for Suspension:

Nitasol 30 ml suspension: Shake the bottle well before adding water. Then add 20 ml of boiled and cooled water (with the help of provided cup) into the bottle and shake well to make 30 ml suspension.

Nitasol 60 ml suspension: Shake the bottle well before adding water. Then add 40 ml of boiled and cooled water (with the help of provided cup) into the bottle and shake well to make 60 ml suspension.

Storage condition:

Store in a cool and dry place & away from light and moisture. The reconstituted suspension should be used within 7 days of preparation.

Presentation:

Nitasol Tablet: Box contains 12 tablets in Alu-Alu blister.

Nitasol 30 ml suspension: Bottle containing dry powder to reconstitute 30 ml suspension.

Nitasol 60 ml suspension: Bottle containing dry powder to reconstitute 60 ml suspension.

Manufactured by:

The IBN SINA Pharmaceutical Industry Ltd.
Shafipur, Gazipur, Bangladesh.