

Nitaxide®

Nitazoxanide

Tablet/Powder for Suspension

Description

Nitaxide® contains the active ingredient, Nitazoxanide, a synthetic antiprotozoal and anthelmintic agent for oral administration.

Indications and Usage

1. Protozoal diarrhoea caused by *Cryptosporidium parvum*, *Giardia* strains (lamblia/intestinalis) and *Entamoeba histolytica*.
2. Diarrhoea caused by rota virus.
3. Wide range of helminth/worm infections; Helminthiasis.
4. Diarrhoea caused by *Giardia* strains that are resistant to other drugs.
5. Fascioliasis (infection caused by fluke/parasite)

Dosage and Administration

Age 1-3 years: 5 ml of Nitaxide® Suspension (100 mg Nitazoxanide) every 12 hours for 3 days.

Age 4-11 years: 10 ml of Nitaxide® Suspension (200 mg Nitazoxanide) every 12 hours for 3 days.

Age ≥ 12 years: Nitaxide® Tablet or 25 ml of Nitaxide® Suspension (500 mg Nitazoxanide) every 12 hours for 3 days. Nitaxide® should be taken with food.

Contraindications

Nitazoxanide is contraindicated in patients with a prior hypersensitivity to Nitazoxanide.

Adverse Effects

Nitazoxanide is well tolerated and minimum side effects such as abdominal discomfort, diarrhoea, nausea and

headache have been reported.

Drug Interactions

At present there are no documented drug-drug interaction.

Precautions

General: The pharmacokinetics of Nitazoxanide in patients with impaired renal or hepatic function have not been studied. Therefore, 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 disease.

Pregnancy and Nursing Mother: Pregnancy Category B. It is not known whether Nitazoxanide is excreted in human milk. Caution should be exercised when Nitazoxanide is administered to a nursing woman.

Paediatric Use: Safety and effectiveness of Nitazoxanide for Oral Suspension in paediatric patients less than one year of age have not been studied.

Direction for Reconstitution

Nitaxide® Powder for Suspension, 30 ml: Shake the bottle to loosen powder. Then add 20 ml boiled and cooled water. To facilitate mixing add water in two steps. After each addition shake vigorously until all the powder is in suspension.

Nitaxide® Powder for Suspension, 60 ml: Shake the bottle to loosen powder. Then add 40 ml boiled and cooled water. To facilitate mixing add water in two steps. After each addition shake vigorously until all the powder is in suspension.

Keep the bottle tightly closed. The reconstituted suspension should be stored in a cool place preferably in a refrigerator and used within 14 days after reconstitution.

Pharmaceutical Precautions

Store in a cool and dry place, protect from light and moisture.

Commercial Pack

Nitaxide® Powder for Suspension: Available in 30 ml and 60 ml bottle. Each 5 ml contains Nitazoxanide INN 100 mg. Nitaxide® Tablet: Box containing 20 tablets in 2 x 10's blister strips. Each tablet contains Nitazoxanide INN 500 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH

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