

Zox[®]

Nitazoxanide

Composition

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

Zox[®] 30 ml suspension : Each 5 ml suspension contains Nitazoxanide INN 100 mg.

Zox[®] 60 ml suspension : Each 5 ml suspension contains Nitazoxanide INN 100 mg.

Description

Nitazoxanide, a synthetic antiprotozoal agent. Nitazoxanide is well absorbed from GIT. 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. Diarrhoea 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.

Side effect

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

Precaution

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

Contraindication

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

Use in 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.

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.

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.

Reconstitution for suspension

Zox[®] 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.

Zox[®] 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.

Pharmaceutical precaution

Store in a cool and dry place, away from light and moisture. Once reconstituted suspension should be used within 7 days.

How supplied

Zox[®] tablet: Box contains 5 X 6 tablets in Alu-Alu blister.

Zox[®] 30 ml suspension: Bottle containing dry powder to reconstitute 30 ml suspension.

Zox[®] 60 ml suspension: Bottle containing dry powder to reconstitute 60 ml suspension.