

Zoxan[®]

Nitazoxanide

Description

Zoxan[®] is the preparation of nitazoxanide, a synthetic antiprotozoal agent.

Mode 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. This results in membrane damage and ultimately dysfunction of the parasite.

Pharmacokinetics

Nitazoxanide is well absorbed from GIT. After absorption it is converted to its active metabolite tizoxanide. In plasma, more than 99% of tizoxanide is bound to proteins. Following oral administration in humans, nitazoxanide is rapidly hydrolyzed to an active metabolite, tizoxanide (desacetyl-nitazoxanide). Tizoxanide then undergoes conjugation, primarily by glucuronidation. 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.

Composition

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

Zoxan[®] 30 ml Suspension: Each 5 ml reconstituted suspension contains Nitazoxanide INN 100 mg.

Zoxan[®] 60 ml Suspension: Each 5 ml reconstituted suspension contains Nitazoxanide INN 100 mg.

Indications

- Diarrhoea caused by *Cryptosporidium parvum* and *Giardia lamblia*.
- Amoebiasis 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.

Contraindications

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

Side effect

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

Use in Pregnancy & Lactation

Pregnancy: This drug should be used during pregnancy only if clearly needed.

Nursing mother: It is not known whether Nitazoxanide is excreted in human milk. Caution should be exercised when Nitazoxanide is administered to a nursing woman.

Precautions

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

Drug interactions

Although no drug-drug interaction studies have been conducted *in vivo*, it is expected that no significant interaction would occur when Nitazoxanide is co-administered with drugs that either are metabolized by or inhibit cytochrome P450 enzymes.

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.

Storage

Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light. Once reconstituted suspension should be used within 7 days.

Packaging

Zoxan[®] Tablet: Each carton contains 10X5 tablets in Alu-PVC blister.

Zoxan[®] 30 ml Suspension: Each carton contains dry powder to reconstitute 30 ml suspension.

Zoxan[®] 60 ml Suspension: Each carton contains dry powder to reconstitute 60 ml suspension.



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