

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Alinia®
<b>Generic Name</b>	nitazoxanide
<b>Drug Manufacturer</b>	Rising Pharma Holding, Inc.

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First Time Generic Approval

#### FDA APPROVAL DATE

November 27, 2020

#### LAUNCH DATE

November 30, 2020

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 213820

#### DISPENSING RESTRICTIONS

None

### Overview

#### INDICATION FOR USE

An antiprotozoal indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*.

Limitations of Use: Alinia® has not been shown to be effective for the treatment of diarrhea caused by *C. parvum* in HIV-infected or immunodeficient patients.

#### MECHANISMS 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. Studies have shown that the PFOR enzyme from *G. lamblia* directly reduces nitazoxanide by transfer of electrons in the absence of ferredoxin. The DNA-derived PFOR protein sequence of *C. parvum* appears to be similar to that of *G. lamblia*. Interference with the PFOR enzyme-dependent electron transfer reaction may not be the only pathway by which nitazoxanide exhibits antiprotozoal activity.

#### DOSE FORM AND STRENGTH

- Alinia® Tablets: 500 mg
- Alinia® for Oral Suspension: 100 mg/5 mL

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### DOSE & ADMINISTRATION

- Alinia® tablets should not be administered to pediatric patients 11 years of age or younger.
- Dosage for treatment of diarrhea caused by *G. lamblia* or *C. parvum*:

Age	Dosage	Duration
1-3 years	5 mL of Alinia® for Oral Suspension (100 mg nitazoxanide) every 12 hours with food.	3 Days
4-11 years	10 mL of Alinia® for Oral Suspension (200 mg nitazoxanide) every 12 hours with food.	
12 years and older	One Alinia® Tablet (500 mg nitazoxanide) every 12 hours with food or 25 mL of Alinia® for Oral Suspension (500 mg nitazoxanide) every 12 hours with food.	

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