FIRST TIME GENERIC APPROVAL

Brand Name	Alinia®
Generic Name	nitazoxanide
Drug Manufacturer	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.	