

Reference number(s)

9-1

Quantity Limit with Age Edit Alinia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	
Alinia	nitazoxanide	

Indications

FDA-approved Indications

Diarrhea caused by Giardia lamblia or Cryptosporidium parvum:

Alinia for Oral Suspension (patients 1 year of age and older) and Alinia Tablets (patients 12 years and older) are indicated for the treatment of diarrhea caused by Giardia lamblia or Cryptosporidium parvum.

Limitations of Use

Alinia for Oral Suspension and Alinia Tablets have not been shown to be effective for the treatment of diarrhea caused by Cryptosporidium parvum in HIV-infected or immunodeficient patients.

Compendial Uses

Human fascioliasis (Fasciola hepatica)^{2,3}

Clostridium difficile colitis^{2,3}

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Limit Criteria

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

These drugs are for short-term acute use; therefore the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.

Drug	1 Month Limit	3 Month Limit	Age Edit
Alinia 100 mg/5 mL Oral Suspension (nitazoxanide)	540 mL per 25 days	Does Not Apply	1 year of age and older
Alinia 500 mg Tablets	20 tablets per 25 days	Does Not Apply	12 years of age and older

References

- 1. Alinia [package insert]. Tampa, FL: Romark Laboratories, L.C.; January 2022.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 4, 2025.
- 3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/04/2025).
- 4. Centers for Disease Control. https://www.cdc.gov/parasites/fasciola/health_professionals/index.html#tx. Accessed February 4, 2025.
- 5. L Clifford McDonald, Dale N Gerding, Stuart Johnson, Johan S Bakken, Karen C Carroll, Susan E Coffin, Erik R Dubberke, Kevin W Garey, Carolyn V Gould, Ciaran Kelly, Vivian Loo, Julia Shaklee Sammons, Thomas J Sandora, Mark H Wilcox, Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), Clinical Infectious Diseases, Volume 66, Issue 7, 1 April 2018, Pages e1–e48, https://doi.org/10.1093/cid/cix1085. Accessed February 4, 2025.