

Nitazoxanide

Is there a treatment for diarrhea caused by Cryptosporidium?

Yes. 1,2 FDA licensed nitazoxanide (Alinia®, Romark Laboratories, Tampa, FL, USA) for treatment of cryptosporidiosis in children aged 1-11 years in November 2002. In June 2004, nitazoxanide was also licensed for older children and adults. It can now be prescribed for all patients ≥ 1 year of age.

What age groups can be treated with nitazoxanide?

In 2004, the FDA licensed nitazoxanide for all persons ≥ 1 year of age. It had previously been licensed in 2002 for only children aged 1-11 years.

What is the dosage used for nitazoxanide?

Immunocompetent Persons ³	
Adult dosage	500 mg BID x 3 days
Pediatric dosage	1-3 years: 100 mg BID x 3 days
	4-11 years: 200 mg BID x 3 days

Nitazoxanide oral suspension (100 mg/5ml; patients \geq 1 year of age) and Nitazoxanide tablets (500 mg; patients \geq 12 years of age) are indicated for the treatment of diarrhea caused by *Cryptosporidium*.

What is the efficacy?

Clinical cure (resolution of diarrhea) rates range from 72-88%. Parasitologic cure (no *Cryptosporidium* detected in stool) rates range from 60-75%. Parasitologic cure rate was a key consideration in developing prevention recommendations that ask people to refrain from swimming for 2 weeks after resolution of symptoms. Retesting of treated persons is not considered necessary.

How rapidly does the drug work?

It may take up to 5 days for diarrhea to resolve in approximately 80% of patients. Because of this and the lower parasitologic cure rate, CDC still recommends that all infected persons, including those who have completed treatment, do not swim for 2 weeks after resolution of symptoms. It is critical that this recommendation is followed to prevent the spread of this chlorine-resistant parasite through public swimming pools and other aquatics venues.

Should patients be re-tested after treatment with nitazoxanide and, if so, when? Health care professionals might consider re-testing stool at least 1 week after the last dose of nitazoxanide only if symptoms do not resolve. In such cases, longer courses of treatment might be needed. Persistent symptoms may also represent re-infection or other causes of illness besides cryptosporidiosis.

My patient is still ill. What other treatment regimens have been tried?

Nitazoxanide appears to be well tolerated and different treatment regimens have been used for a variety of infections. Immunocompetent persons with cryptosporidiosis have been treated with multiple 3-day courses of nitazoxanide.⁵ Seven-day courses have also been used in early studies for cryptosporidiosis and other parasitic infections.^{6,7} AIDS patients with *Cryptosporidium*-associated diarrhea received the drug for 28 days.⁸

What about patients with compromised immune systems?

Nitazoxanide has been approved for treatment of diarrhea caused by *Cryptosporidium* in people with healthy immune systems. It is presently not approved to treat immunodeficient persons because nitazoxanide oral suspension and nitazoxanide tablets have not been shown to be superior

to placebo for the treatment of diarrhea caused by *Cryptosporidium* in HIV-infected or immunodeficient patients.¹

What should I tell my patients with cryptosporidiosis about swimming?

Cryptosporidium now causes over half of the reported waterborne disease outbreaks associated with swimming in chlorinated public swimming pools. ⁹ Cryptosporidium's chlorine resistance and documented excretion for weeks after resolution of symptoms has led CDC and The American Academy of Pediatrics ¹⁰ to recommend that all persons refrain from swimming until 2 weeks after resolution of symptoms.

References

- ¹ Fox LM, Saravolatz LD. Nitazoxanide: a new thiazolide antiparasitic agent. Clin Infect Dis. 2005 40(8):1173-80.
- ² White, AC Jr. Nitazoxanide: a new broad spectrum antiparasitic agent. Expert Rev Anti-infect Ther 2004 2(1):43-49.
- ³ The Medical Letter, Drugs for Parasitic Infections. 2007. See http://www.cdc.gov/crypto/pdfs/medlet_crypto.pdf. Also see FDA prescribing information.
- ⁴ Rossignol JF, Ayoub A, Ayers MS. Treatment of diarrhea caused by *Cryptosporidium parvum*: a prospective randomized, double-blind, placebo-controlled study of Nitazoxanide. J Infect Dis. 2001 184(1):103-6.
- ⁵ Diaz E, Mondragon J, Ramirez E, Bernal R. Epidemiology and control of intestinal parasites with nitazoxanide in children in Mexico. Am J Trop Med Hyg. 2003 68(4):384-5.
- ⁶ Doumbo O, Rossignol JF, Pichard E, Traore HA, Dembele TM, Diakite M, Traore F, Diallo DA. Nitazoxanide in the treatment of cryptosporidial diarrhea and other intestinal parasitic infections associated with acquired immunodeficiency syndrome in tropical Africa. Am J Trop Med Hyg. 1997 56(6):637-9.
- ⁷ Favennec L, Jave Ortiz J, Gargala G, Lopez Chegne N, Ayoub A, Rossignol JF. Double-blind, randomized, placebo-controlled study of nitazoxanide in the treatment of fascioliasis in adults and children from northern Peru. Aliment Pharmacol Ther. 2003 17(2):265-70.
- ⁸ Rossignol JF, Hidalgo H, Feregrino M, Higuera F, Gomez WH, Romero JL, Padierna J, Geyne A, Ayers MS. A double-'blind' placebo-controlled study of nitazoxanide in the treatment of cryptosporidial diarrhea in AIDS patients in Mexico. Trans R Soc Trop Med Hyg. 1998 92(6):663-6.
- ⁹ Dziuban EJ, Liang JL, Craun GF, Hill V, Yu PA, Painter J, Moore MR, Calderon RL, Roy SL, Beach MJ; Centers for Disease Control and Prevention (CDC). Surveillance for waterborne disease and outbreaks associated with recreational water--United States, 2003-2004. MMWR Surveill Summ. 2006 55(12):1-30.
- ¹⁰ The American Academy of Pediatrics. In: Pickering LK, Baker CJ, Long SS, McMillan JA, eds. Red Book: 2006 Report of the Committee on Infectious Diseases. 27th ed. Elk Grove Village IL.

This fact sheet is for information only and is not meant to be used for self-diagnosis or as a substitute for consultation with a health care provider. If you have any questions about the disease described above or think that you may have a parasitic infection, consult a health care provider.

From http://www.cdc.gov/crypto/factsheets/tx.html



