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NITAZOXANIDE: A REVIEW OF ITS USE IN THE TREATMENT OF GASTROINTESTINAL INFECTIONS

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ABSTRACT

Nitazoxanide is a new thiazolide antiparasitic agent. Nitazoxanide (AliniaR, DaxonR, DexidexR, ParamixR, KidonaxR, ColufaseR, AnnitaR) has *in vitro* activity against a variety of microorganisms, including a broad range of protozoa and helminths. Nitazoxanide is effective in the treatment of protozoal and helminthic infections, including *Cryptosporidium parvum* or *Giardia lamblia*, in immunocompetent adults and children, and is generally well tolerated. Nitazoxanide is a first-line choice for the treatment of illness caused by *C. parvum* or *G. lamblia* infection in immunocompetent adults and children, and is an option to be considered in the treatment of illnesses caused by other protozoa and/or helminths. Nitazoxanide has been licensed for the treatment of Giardia intestinalis–induced diarrhea in patients 1 year of age and Cryptosporidum-induced diarrhea in children aged 1–11 years.

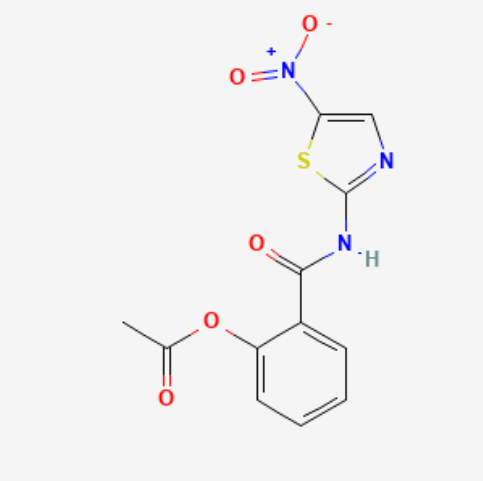
KEYWORDS: diarrhea, antiparasitic agents, infections, protozoa, nitazoxanide.

INTRODUCTION

More than 30 years after the introduction of the nitroimidazoles and benzimidazoles, there have been few, new innovations in treating intestinal parasitic infections. Meanwhile, these infections remain among the leading causes of morbidity and mortality in the world today. With this background, it is noteworthy to recognize recent advances with the development of nitazoxanide* (NTZ), a product developed specifically for the treatment of intestinal parasitic infections. The spectrum of activity against common, emerging and resistant intestinal

protozoa, and common intestinal helminths by NTZ offers potential for significant improvement in treatment outcomes for patients with intestinal parasitosis.

Structure of NTZ



IUPAC Name: [2-[(5-nitro-1,3-thiazol-2-yl)carbamoyl]phenyl] acetate.

Mechanism of action

Studies of protozoa and anaerobic bacteria have shown that nitazoxanide inhibits pyruvate-ferredoxin oxidoreductase (PFOR), an enzyme essential to anaerobic energy metabolism.[12] Unlike nitromidazoles, such as metronidazole, the main target of nitazoxanide in protozoa and anaerobic bacteria appears to be a critical pathway in anaerobic energy metabolism, the pyruvate: ferrodoxin oxidoreductase (PFOR) enzyme – dependent electron transfer reaction.(4.6, 9 Nitazoxanide is a noncompetitive inhibitor of the PFOR system in the protozoan species, Entamoeba histolytica, G.lamblia and Trichomonas vaginalis and the bacterial species Campylobacter jejuni, Clostrodium difficile C. perfringens and Helicobacter pylori. It has been proposed that Nitazoxanide inhibitis the first step in the PFOR reaction by interfering with the thiamine pyrophosphate co factor, as opposed to the interacting with PFOR target. This enzymatic mechanism of action may avoid potential mutation – based drug resistance.[9]

Other potential mechanisms of action of Nitazoxanide remain to be elucidated as there are some organisms that lack the PFOR target and some organisms resistant to metronidazole (which also targets the PFOR reaction) are susceptible to nitazoxanide derivatives.[5,10,11]

There is limited data on the potential for organisms to develop resistance to nitazoxanide. No Nitazoxanide resistance was observed in the H. pylori strains after nitazoxanide concentration

gradient subculturing, but nitazoxanide resistance has been generated in two G. lamblia strains in vitro.[12]

Pharmacokinetic Properties

The pharmacokinetic properties of nitazoxanide and its active metabolite tizoxanide, have been examined in healthy volunteers after single-[39-41] and multiple-dose[42] oral administration of nitazoxanide in tablet form. Data from the US prescribing information on adult and paediatric patients receiving nitazoxanide tablets or oral suspension are also included.[4] The pharmacokinetic properties of nitazoxanide have not been studied in patients with impaired renal and/or hepatic function or in the elderly.[4]

Following the absorption of nitazoxanide in the gut, the main metabolite formed is tizoxanide; a second metabolite (tizoxanide glucuronide) has been identified but it is not an active metabolite.[39] The hydrolysation to tizoxanide and subsequent conjugation to tizoxanide glucuronide occurs so rapidly that Nitaxozanide is not detectable in plasma.[4,39,41]

SUMMARY

Nitazoxanide is a new nitrothiazole compound with broadspectrum activity against numerous intestinal protozoa, helminths, and anaerobic bacteria. It is presently approved to treat infections due to *G. intestinalis* in children and adults and infections due to *Cryptosporidium* species in children. Approval for use in adults with *Cryptosporidium* infection and the immunocompromised population is on the horizon. Nitazoxanide is an important new addition to the antiparasitic pharmacopeia. The drug has few side effects and requires a short course of treatment. Nevertheless, a need remains for further studies of its molecular mechanisms of action, bioavailability, and drug interactions to learn whether it can be safely used in a variety of patient groups. Because the majority of parasitic infections occur in the developing world, further data about drug potency and stability are also needed to support its widespread use in this context. Similarly, clinical and pharmacological data on absorption, dosage, and duration of therapy in patients with AIDS and chronic cryptosporidiosis are necessary. In view of its unique mechanism of action, nitazoxanide should be considered for further clinical evaluation in the treatment of parasitic infections (e.g., in combination with paromomycin or azithromycin for treatment of cryptosporidiosis and in combination with albendazole for treatment of intestinal helminth infections) and in reducing the emergence of metronidazole resistance, particularly with *Giardia* and *H. pylori*. Additional clinical trial data that would expand our knowledge of nitazoxanide's utility in these contexts is important.

With these questions answered, nitazoxanide may represent a significant advance in the treatment of intestinal parasitic infections worldwide.

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