

N/A- nitazoxanide tablet
Lupin Pharmaceuticals, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NITAZOXANIDE TABLETS safely and effectively. See full prescribing information for NITAZOXANIDE TABLETS .

NITAZOXANIDE tablets, for oral use

Initial U.S. Approval: 2002

----- **INDICATIONS AND USAGE** -----

Nitazoxanide Tablets is an antiprotozoal indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* in patients 12 years of age and older (1).

Limitations of Use:

Nitazoxanide Tablets has not been shown to be effective for the treatment of diarrhea caused by *C. parvum* in HIV-infected or immunodeficient patients (1).

----- **DOSAGE AND ADMINISTRATION** -----

- The recommended dosage of Nitazoxanide Tablets in patients 12 years and older is 500 mg orally every 12 hours with food for 3 days.
- Nitazoxanide Tablets should not be administered to pediatric patient 11 years of age or younger (2.1)

----- **DOSAGE FORMS AND STRENGTHS** -----

Tablets: 500 mg (3.1)

----- **CONTRAINDICATIONS** -----

Hypersensitivity (4.1)

----- **ADVERSE REACTIONS** -----

The most common adverse reactions in $\geq 2\%$ of patients were abdominal pain, headache, chromaturia, and nausea (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Romark at 813-282-8544 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----- **DRUG INTERACTIONS** -----

Competition for binding sites may occur when administered concurrently with other highly plasma protein-bound drugs with narrow therapeutic indices. Monitor for adverse reactions (7).

Revised: 12/2021

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Nitazoxanide Tablets are indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* in patients 12 years and older.

Limitations of Use

Nitazoxanide Tablets have not been shown to be effective for the treatment of diarrhea caused by *Cryptosporidium parvum* in HIV-infected or immunodeficient patients [see *Clinical Studies (14.2)*].

2 DOSAGE AND ADMINISTRATION

The recommended dosage of Nitazoxanide Tablets in patient 12 years and older is 500 mg orally every 12 hours with food for 3 days.

Nitazoxanide Tablets should not be administered to pediatric patients 11 years of age or younger because a single tablet contains a greater amount of nitazoxanide than the recommended dosing in this pediatric age group. Nitazoxanide Tablets are not interchangeable with Nitazoxanide for Oral Suspension [see Clinical Pharmacology (12.3)]

3 DOSAGE FORMS AND STRENGTHS

Round, yellow, film-coated tablets debossed with 77 on one side and plain on the other side. Each tablet contains 500 mg of nitazoxanide.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

Nitazoxanide Tablets are contraindicated in patients with a prior hypersensitivity to nitazoxanide or any other ingredient in the formulations.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of nitazoxanide was evaluated in 2177 HIV-uninfected subjects who received nitazoxanide at the recommended dose for at least three days. In pooled controlled clinical trials involving 536 HIV-uninfected subjects treated with nitazoxanide, the most common adverse reactions were abdominal pain, headache, chromaturia and nausea ($\geq 2\%$).

Safety data were analyzed separately for 280 HIV-uninfected subjects ≥ 12 years of age receiving nitazoxanide at the recommended dose for at least three days in 5 placebo-controlled clinical trials.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of nitazoxanide. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The following is a list of adverse reactions spontaneously reported with Nitazoxanide Tablets which were not included in clinical trial listings:

Gastrointestinal disorders: diarrhea, gastroesophageal reflux disease

Nervous System disorders: dizziness

Respiratory, thoracic and mediastinal disorders: dyspnea

Skin and subcutaneous tissue disorders: rash, urticaria

7 DRUG INTERACTIONS

7.1 Highly Protein Bound Drugs with Narrow Therapeutic Indices

Tizoxanide (the active metabolite of nitazoxanide) is highly bound to plasma protein ($>99.9\%$). Therefore, monitor for adverse reactions when administering nitazoxanide concurrently with other highly plasma protein-bound drugs with narrow therapeutic indices, as competition for binding sites may occur (e.g., warfarin).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no data with nitazoxanide in pregnant women to inform a drug-associated risk. No teratogenicity or fetotoxicity was observed in animal reproduction studies with administration of nitazoxanide to pregnant rats and rabbits during organogenesis at exposure 30 and 2 times, respectively, the exposure at the maximum recommended human dose of 500 mg twice daily based on body surface area (BSA).

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

Nitazoxanide was administered orally to pregnant rats at doses of 0, 200, 800 or 3200 mg/kg/day on gestation days 6 to 15. Nitazoxanide produced no evidence of systemic maternal toxicity when administered once daily via oral gavage to pregnant female rats at levels up to 3200 mg/kg/day during the period of organogenesis .

In rabbits, nitazoxanide was administered at doses of 0, 25, 50, or 100 mg/kg/day on gestation days 7 to 20. Oral treatment of pregnant rabbits with nitazoxanide during organogenesis resulted in minimal maternal toxicity and no external fetal anomalies.

8.2 Lactation

Risk Summary

No information regarding the presence of nitazoxanide in human milk, the effects on the breastfed infant, or the effects on milk production is available. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for nitazoxanide and any potential adverse effects on the breastfed infant from nitazoxanide or from the underlying maternal condition.

8.4 Pediatric Use

The safety and efficacy of Nitazoxanide Tablets for the treatment of diarrhea caused by *G. lamblia* or *C. parvum* in pediatric patients 12 to 17 years of age has been established based on three (3) randomized, controlled studies with 47 pediatric subjects treated with Nitazoxanide Tablets [see *Clinical Studies (14)*].

A single Nitazoxanide Tablet contains a greater amount of nitazoxanide than is recommended for use in pediatric patients 11 years or younger. Therefore, Nitazoxanide Tablets should not be administered to pediatric patients 11 years of age or younger [see *Dosage and Administration (2)*].

8.5 Geriatric Use

Clinical studies of Nitazoxanide Tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, the greater frequency of decreased hepatic, renal, or cardiac function, and of

concomitant disease or other drug therapy in elderly patients should be considered when prescribing Nitazoxanide Tablets.

8.6 Renal and Hepatic Impairment

The pharmacokinetics of nitazoxanide in patients with compromised renal or hepatic function has not been studied.

8.7 HIV-Infected or Immunodeficient Patients

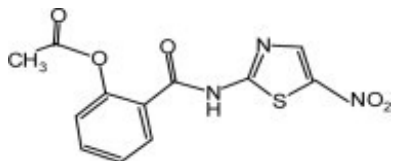
Nitazoxanide Tablets have not been studied for the treatment of diarrhea caused by *G. lamblia* in HIV-infected or immunodeficient patients. Nitazoxanide Tablets have not been shown to be superior to placebo for the treatment of diarrhea caused by *C. parvum* in HIV-infected or immunodeficient patients [see *Clinical Studies (14)*].

10 OVERDOSAGE

Limited information on nitazoxanide overdose is available. In the event of overdose, gastric lavage may be appropriate soon after oral administration. Patients should be observed and given symptomatic and supportive treatment. There is no specific antidote for overdose with nitazoxanide. Because nitazoxanide is highly protein bound (>99.9%), dialysis is unlikely to significantly reduce plasma concentrations of the drug.

11 DESCRIPTION

Nitazoxanide Tablets contain the active ingredient, nitazoxanide, a synthetic antiprotozoal for oral administration. Nitazoxanide is a light yellow crystalline powder. It is poorly soluble in ethanol and practically insoluble in water. Chemically, nitazoxanide is 2-acetyloxy- *N*-(5-nitro-2-thiazolyl)benzamide. The molecular formula is C₁₂H₉N₃O₅S and the molecular weight is 307.3. The structural formula is:



Nitazoxanide Tablets contain 500 mg of nitazoxanide and the following inactive ingredients: maize starch, pregelatinized corn starch, hydroxypropyl methylcellulose, sucrose, sodium starch glycolate, talc, magnesium stearate, soy lecithin, polyvinyl alcohol, xanthan gum, titanium dioxide, D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, and FD&C Blue No. 2 Aluminum Lake.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Nitazoxanide is an antiprotozoal [see *Microbiology (12.4)*].

12.3 Pharmacokinetics

Absorption

Single Dosing:

Following oral administration of Nitazoxanide Tablet, the parent drug, nitazoxanide, is not detected in plasma. The pharmacokinetic parameters of the metabolites, tizoxanide and tizoxanide glucuronide are shown in Table 1 below.

Table 1. Mean (+/- SD) plasma pharmacokinetic parameters of tizoxanide and tizoxanide glucuronide following administration of a single dose of one 500 mg Nitazoxanide Tablet with food to subjects ≥ 12 years of age

Age	Tizoxanide			Tizoxanide Glucuronide		
	C _{max} (µg/mL)	T _{max} (hr)*	AUC _t (µg•hr/mL)	C _{max} (µg/mL)	T _{max} (hr)*	AUC _t (µg•hr/mL)
12 - 17 years	9.1 (6.1)	4.0 (1-4)	39.5 (24.2)	7.3 (1.9)	4.0 (2-8)	46.5 (18.2)
>18 years	10.6 (2.0)	3.0 (2-4)	41.9 (6.0)	10.5 (1.4)	4.5 (4-6)	63.0 (12.3)

*T_{max} is given as a Mean (Range)

Multiple dosing:

Following oral administration of a single Nitazoxanide Tablet every 12 hours for 7 consecutive days, there was no significant accumulation of nitazoxanide metabolites tizoxanide or tizoxanide glucuronide detected in plasma.

Bioavailability:

Nitazoxanide for oral suspension is not bioequivalent to Nitazoxanide Tablets. The relative bioavailability of the suspension compared to the tablet was 70%.

When Nitazoxanide Tablets are administered with food, the AUC_t of tizoxanide and tizoxanide glucuronide in plasma is increased almost two-fold and the C_{max} is increased by almost 50%.

Nitazoxanide Tablets were administered with food in clinical trials and hence they are recommended to be administered with food [see Dosage and Administration (2.1)]

Distribution

In plasma, more than 99% of tizoxanide is bound to proteins.

Elimination

Metabolism

Following oral administration in humans, nitazoxanide is rapidly hydrolyzed to an active metabolite, tizoxanide (desacetyl-nitazoxanide). Tizoxanide then undergoes conjugation, primarily by glucuronidation.

Excretion

Tizoxanide is excreted in the urine, bile and feces, and tizoxanide glucuronide is excreted in urine and bile. Approximately two-thirds of the oral dose of nitazoxanide is excreted in the feces and one-third in the urine.

Specific Populations

Pediatric Patients

The pharmacokinetics of tizoxanide and tizoxanide glucuronide following administration of Nitazoxanide Tablets in pediatric patients 12-17 years of age are provided above in Table 1.

Drug Interaction Studies

In vitro studies have demonstrated that tizoxanide has no significant inhibitory effect on cytochrome P450 enzymes.

12.4 MICROBIOLOGY

Mechanism 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.

Resistance

A potential for development of resistance by *C. parvum* or *G. lamblia* to nitazoxanide has not been examined.

Antimicrobial Activity

Nitazoxanide and its metabolite, tizoxanide, are active *in vitro* in inhibiting the growth of (i) sporozoites and oocysts of *C. parvum* and (ii) trophozoites of *G. lamblia*.

Susceptibility Test Methods

For protozoa such as *C. parvum* and *G. lamblia*, standardized tests for use in clinical microbiology laboratories are not available.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term carcinogenicity studies have not been conducted.

Mutagenesis

Nitazoxanide was not genotoxic in the Chinese hamster ovary (CHO) cell chromosomal aberration assay or the mouse micronucleus assay. Nitazoxanide was genotoxic in one tester strain (TA 100) in the Ames bacterial mutation assay.

Impairment of Fertility

Nitazoxanide did not adversely affect male or female fertility in the rat at 2400 mg/kg/day (approximately 20 times the clinical adult dose adjusted for body surface area).

14 CLINICAL STUDIES

14.1 Diarrhea Caused by *G. lamblia*

Diarrhea caused by *G. lamblia* in adults and adolescents 12 years of age or older:

In a double-blind, controlled trial (Study 1) conducted in Peru and Egypt in adults and adolescents with diarrhea and with one or more enteric symptoms (e.g., abdominal pain, nausea, vomiting, fever, abdominal distention, loss of appetite, flatulence) caused by *G. lamblia*, a three-day course of treatment with Nitazoxanide Tablets administered 500 mg BID was compared with a placebo tablet for 3 days. A second double-blind, controlled trial (Study 2) conducted in Egypt in adults and adolescents with diarrhea and with or without enteric symptoms (e.g., abdominal colic, abdominal tenderness, abdominal cramps, abdominal distention, fever, bloody stool) caused by *G. lamblia* compared Nitazoxanide Tablets administered 500 mg BID for 3 days to a placebo tablet. For both of these studies, clinical response was evaluated 4 to 7 days following the end of treatment. A clinical response of 'well' was defined as 'no symptoms, no watery stools and no more than 2 soft stools with no hematochezia within the past 24 hours' or 'no symptoms and no unformed stools within the past 48 hours.' The following clinical response rates were obtained:

Table 2. Adult and Adolescent Patients with Diarrhea Caused by *G. lamblia* Clinical Response Rates* 4 to 7 Days Post-therapy

% (Number of Successes/Total)

	Nitazoxanide Tablets	Placebo Tablets
Study 1	85% (46/54) ¶	44% (12/27)
Study 2	100% (8/8)	30% (3/10)

* Includes all patients randomized with *G. lamblia* as the sole pathogen. Patients failing to complete the studies were treated as failures.

¶ Clinical response rates statistically significantly higher when compared to placebo.

Some patients with 'well' clinical responses had *G. lamblia* cysts in their stool samples 4 to 7 days following the end of treatment. The relevance of stool examination results in these patients is unknown. Patients should be managed based upon clinical response to treatment.

14.2 Diarrhea Caused by *C. parvum*

Diarrhea caused by *C. parvum* in adults and adolescents 12 years of age or older:

In a double-blind, controlled trial conducted in Egypt in adults and adolescents with diarrhea and with or without enteric symptoms (e.g., abdominal pain/cramps, nausea, vomiting) caused by *C. parvum*, a three-day course of treatment with Nitazoxanide

Tablets administered 500 mg BID was compared with a placebo tablet for 3 days. Clinical response was evaluated 4 to 7 days following the end of treatment. A clinical response of 'well' was defined as 'no symptoms, no watery stools and no more than 2 soft stools within the past 24 hours' or 'no symptoms and no unformed stools within the past 48 hours.' The following clinical response rates were obtained:

Table 3. Clinical Response Rates in Adult and Adolescent Patients 4 to 7 Days Post-therapy

% (Number of Successes/Total)

	Nitazoxanide Tablets	Placebo Tablets
Intent-to-treat analysis*	96% (27/28) ¶	41% (11/27)

* Includes all patients randomized with *C. parvum* as the sole pathogen. Patients failing to complete the study were treated as failures.

¶ Clinical response rates statistically significantly higher when compared to placebo.

In a second double-blind, placebo-controlled trial of Nitazoxanide Tablets conducted in Egypt in adults and adolescents with diarrhea and with or without enteric symptoms (e.g., abdominal colic, abdominal cramps, epigastric pain) caused by *C. parvum* as the sole pathogen, clinical and parasitological response rates showed a similar trend to the first study. Clinical response rates, evaluated 2 to 6 days following the end of treatment, were 71% (15/21) in the nitazoxanide group and 42.9% (9/21) in the placebo group.

Some patients with 'well' clinical responses had *C. parvum* oocysts in their stool samples 4 to 7 days following the end of treatment. The relevance of stool examination results in these patients is unknown. Patients should be managed based upon clinical response to treatment.

16 HOW SUPPLIED/STORAGE AND HANDLING

Nitazoxanide Tablets are round, yellow, film-coated tablets debossed with 77 on one side and plain on the other side. Each tablet contains 500 mg of nitazoxanide. The tablets are packaged in HDPE bottles of 12 and 30 tablets.

Bottles of 12 tablets NDC 43386-405-12

Bottles of 30 tablets NDC 43386-405-03

Store the tablets at 25 °C (77 °F); excursions permitted to 15 °C-30 °C (59 °F-86 °F). [See USP Controlled Room Temperature]

17 PATIENT COUNSELING INFORMATION

Advise patients and parents/caregivers of pediatric patients taking Nitazoxanide Tablets of the following information:

Dosage and Administration:

Nitazoxanide Tablets should be taken with food.

Drug-drug Interactions:

Avoid concurrent warfarin use.

MANUFACTURER INFORMATION

Manufactured By:

Romark Laboratories, L.C.

Tampa, FL 33607

Telephone: 813-282-8544, Fax: 813-282-1162

E-mail: customer.service@romark.com

Website: www.romark.com

Distributed by:

Lupin Pharmaceuticals, Inc.

Baltimore, MD 21202

SAP code: 266925 Iss.: 12/2021

Nitazoxanide Tablets - 30 ct Label

NDC 43386-405-03

Nitazoxanide Tablets

500 mg

Rx Only

LUPIN 30 TABLETS

NDC 43386-405-03

Nitazoxanide Tablets

500 mg

Rx Only

LUPIN

30 Tablets

STORAGE AND STABILITY:
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature]

DOSAGE AND ADMINISTRATION:
Age ≥ 12 years: one tablet (500 mg nitazoxanide) every 12 hours for 3 days, with food. Please see accompanying prescribing information. This bottle contains 30 tablets. Each tablet contains 500 mg nitazoxanide.

Distributed by:
Lupin Pharmaceuticals, Inc.
Baltimore, MD 21202
SAP code: 266927 Iss. 12/2020

N
3 43386-405-12 1
266927-12-2020

Unvarnished Area
18 mm x 55 mm

Nitazoxanide Tablets - 30 ct Carton

NDC 43386-405-03

Nitazoxanide Tablets

500 mg

Rx Only

LUPIN 30 Tablets



Nitazoxanide Tablets - 12 ct Label

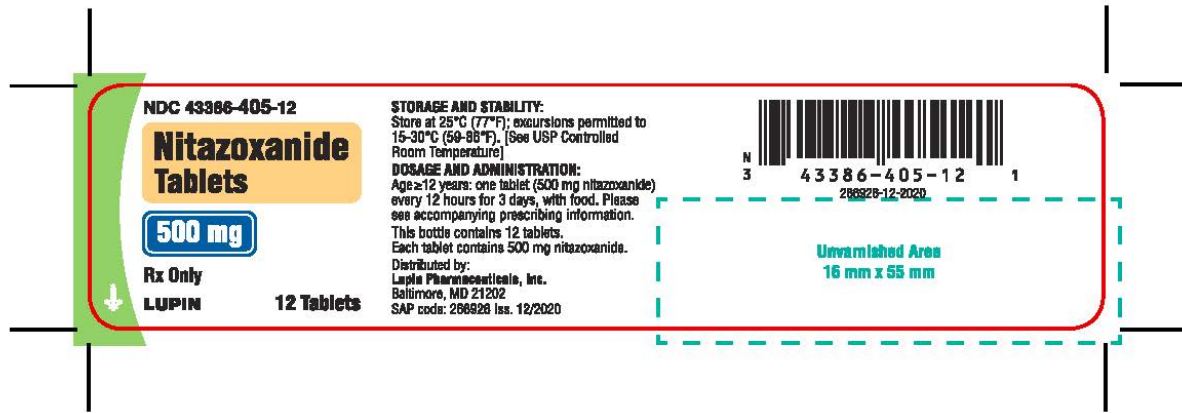
NDC 43386-405-12

Nitazoxanide Tablets

500 mg

Rx only

LUPIN 12 Tablets



Nitazoxanide Tablets - 12 ct Carton

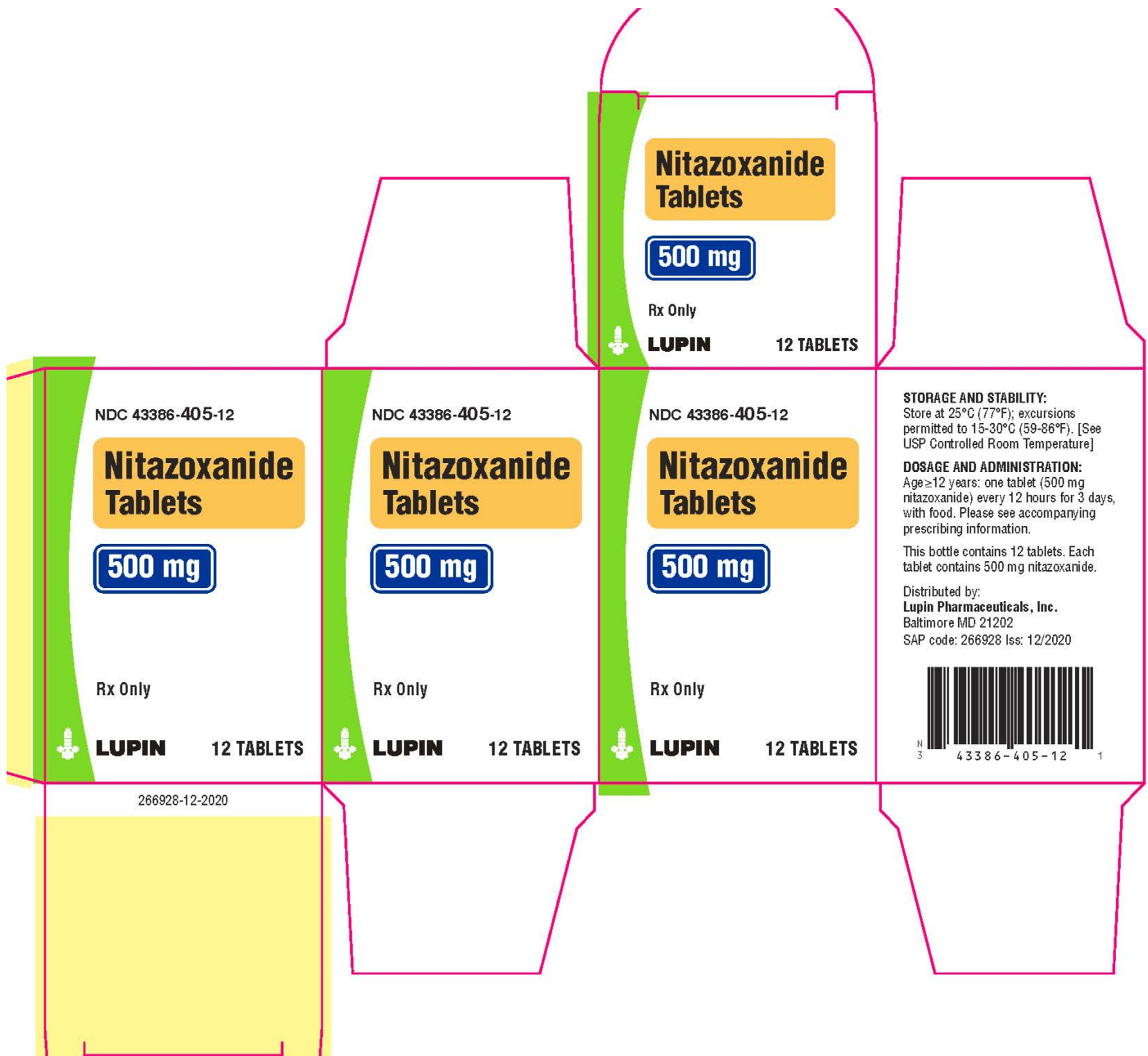
NDC 43386-405-12

Nitazoxanide Tablets

500 mg

Rx only

LUPIN 12 Tablets



N/A

nitazoxanide tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43386-405
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITAZOXANIDE (UNII: SOA12P041N) (NITAZOXANIDE - UNII:SOA12P041N)	NITAZOXANIDE	500 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SUCROSE (UNII: C151H8M554)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	yellow (yellow)	Score	no score
Shape	ROUND (ROUND)	Size	13mm
Flavor		Imprint Code	77
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43386-405-03	30 in 1 CARTON	02/17/2021	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:43386-405-12	12 in 1 CARTON	02/17/2021	
2		12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021497	02/17/2021	

Labeler - Lupin Pharmaceuticals, Inc. (089153071)

Registrant - Romark Laboratories, L.C. (877685123)

Establishment

Name	Address	ID/FEI	Business Operations
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Catalent Pharma Solutions, LLC		014167995	analysis(43386-405)
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Establishment

Name	Address	ID/FEI	Business Operations
Neolpharma, Inc.		078709787	manufacture(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
Romark Global Pharma, LLC		080015267	analysis(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
Romark Global Pharma, LLC		117034720	manufacture(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	pack(43386-405) , label(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
Whitehouse Analytical Laboratories, LLC		138628008	analysis(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Puerto Rico, Inc.		143814544	analysis(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
PACE Analytical Inc.		362250102	analysis(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
Romark Belgium, BVBA		370420271	api manufacture(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Pharma Solutions, LLC		825745131	manufacture(43386-405)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Pharma Solutions, LLC		829672745	manufacture(43386-405)