#### HEARTBURN RELIEF 24 HOUR- lansoprazole capsule, delayed release OUR FAMILY (Nash Finch Company)

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#### **DRUG FACTS**

#### Active ingredient (in each capsule)

Lansoprazole 15 mg

#### Purpose

Acid reducer

#### Use

- treats frequent heartburn (occurs **<u>2 or more</u>** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

## WARNINGS

Allergy alert: Do not use if you are allergic to lansoprazole

#### Do not use

• if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

## Ask a doctor before use if you have

- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

## Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

# Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

# If pregnant or breast-feeding

ask a health professional before use.

## Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

## Directions

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

## <u>14-Day Course of Treatment</u>

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

# <u>Repeated 14-Day Courses (if needed)</u>

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor. Patients should use the lowest dose and shortest duration of this therapy.
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

## Other information

- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.
- store at 20°-25°C (68°-77°F)
- keep product out of high heat and humidity
- protect product from moisture

## Inactive ingredients

colloidal silicon dioxide, D & C Red No. 33, D & C Yellow No. 10, FD & C Blue No. 1, FD & C Red No. 40, gelatin, hypromellose, magnesium carbonate, methacrylic acid copolymer dispersion, polyethylene glycol, polysorbate 80, sucrose, sugar spheres, talc, titanium dioxide

## Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

Compare to the active ingredient in Prevacid® 24 HR\*

\*Prevacid® 24 HR is a registered trademark of Takeda Pharmaceuticals North America, Inc., and is used under license. ©2012 Novartis Consumer Health. Inc

## **HEARTBURN RELIEF 24 HOUR™**

Lansoprazole Delayed- Release capsules, 15 mg

- may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically proven to treat frequent heartburn

#### ACID REDUCER

#### **Sodium Free**

#### **Product of India**

# KEEP OUTER CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

TAMPER-EVIDENT BOTTLE: DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED for YOUR PROTECTION" OR DARK BLUE TO BLACK GELATIN BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.

#### **Product Label**



Lansoprazole delayed release capsules 15 mg

HEARTBURN RELIEF 24 HOUR lansoprazole capsule, delayed release							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70253-019(NDC:55648-140)				
Route of Administration	ORAL						

Ingredient Name				asis of Strength	Strength	
LANSOPRAZOLE (UNII: 0K5C5T2QPG) (LANSOPRAZOLE - UNII:0K5C5T2QPG) LANSOPRAZOLE						
Inactive Ingredier	ıts					
Ingredient Name						
D&C RED NO.33 (UNII	:9DBA0SBB0L)					
D&C YELLOW NO. 10	(UNII: 35SW5USQ3G)					
FD&C BLUE NO. 1 (UN	II: H3R47K3TBD)					
FD&C RED NO.40 (UN	II: WZB9127XOA)					
<b>GELATIN</b> (UNII: 2G86Q	N327L)					
HYPROMELLOSES (UI	NII: 3NXW29V3WO)					
MAGNESIUM CARBONATE (UNII: 0E53J927NA)						
POLYETHYLENE GLY	COLS (UNII: 3WJQ0SDW1A)					
POLYSORBATE 80 (U	NII: 6OZP39ZG8H)					
SILICON DIOXIDE (UN	III: ETJ7Z6XBU4)					
STARCH, CORN (UNII:	O8232NY3SJ)					
SUCROSE (UNII: C151H	8 M554)					
TALC (UNII: 7SEV7J4R1	lU)					
TITANIUM DIO XIDE (U	JNII: 15FIX9V2JP)					
METHACRYLIC ACID -	METHYL METHACRYLATE COPO	LYMER (1:1) (UN	II: 74G4R6TH13)			
Product Characte	ristics					
	ristics PINK, GREEN	Score		no score		
<b>Product Characte</b> Color Shape		Score Size		no score 16mm		
Color Shape	PINK, GREEN		le			
Color Shape	PINK, GREEN	Size	le	16 mm		
Color Shape Flavor	PINK, GREEN	Size	le	16 mm		
Color Shape Flavor Contains	PINK, GREEN	Size	le	16 mm		
Color Shape Flavor Contains Packaging	PINK, GREEN	Size Imprint Coc	le g Start Date	16 mm	End Date	
Color Shape Flavor Contains Packaging # Item Code	PINK, GREEN CAPSULE	Size Imprint Coc		16 mm w140	End Date	
Color Shape Flavor Contains Packaging	PINK, GREEN CAPSULE PAckage Description	Size Imprint Coc		16 mm w140	End Date	
Color Shape Flavor Contains	PINK, GREEN CAPSULE Package Description 1 in 1 CARTON	Size Imprint Coc		16 mm w140	End Date	
Color Shape Flavor Contains	PINK, GREEN CAPSULE Package Description 1 in 1 CARTON 14 in 1 BOTTLE	Size Imprint Coc		16 mm w140	End Date	
S hape Flavor Contains	PINK, GREEN CAPSULE Package Description 1 in 1 CARTON 14 in 1 BOTTLE	Size Imprint Cod		16mm w140 Marketing F	End Date	

Labeler - OUR FAMILY (Nash Finch Company) (006962294)

**Registrant** - P and L Development of New York Corporation (800014821)