# **EQUALINE LANSOPRAZOLE- lansoprazole capsule, delayed release United Natural Foods, Inc. dba UNFI**

-----

SuperValu Inc. Lansoprazole 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 a prescription drug. Acid reducers may interact with certain prescription drugs.

# 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
- you develop a rash or joint pain

# If pregnant or breast-feeding,

ask a health care professional before use.

# Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

### **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

# **14-Day Course of Treatment**

- 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

# Repeated 14-Day Courses (if needed)

- 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
- 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 and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture
- close cap tightly after use

# **Inactive ingredients**

D&C red no. 28, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, gelatin, hypromellose, low substituted hydroxypropyl cellulose, mannitol, meglumine, methacrylic acid copolymer, pharmaceutical ink, polyethylene glycol, polysorbate 80, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide

### Questions or comments?

1-855-423-2630

# Package/Label Principal Display Panel

**EQUALINE**®

compare to Prevacid® 24 HR active ingredient

24 HOUR

lansoprazole

delayed-release capsules 15mg (acid reducer)

- may take 1 to 4 days for full effect
- sodium free

treats frequent heartburn

actual size

14 capsules

one14-day course of treatment

# **EQUALINE®**

# 24 HOUR lansoprazole

delayed-release capsules 15 mg (acid reducer)

#### Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
   Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
  If you smoke, quit smoking.

# **EQUALINE®**

NDC 41163-150-01

compare to Prevacid®24 HR active ingredient\*

# 24 HOUR lansoprazole

delayed-release capsules 15 mg (acid reducer)

- may take 1 to 4 days for full effect
- sodium free

treats frequent heartburn

14 capsules

one 14-day course of treatment



\*This product is not manufactured or distributed by Takeda Pharmaceuticals U.S.A., Inc., owner of the registered trademark Prevacid®. Distributed by UNFI, Providence, RI 02908 USA



100% Quality Like it or let us make it right. 855-423-2630

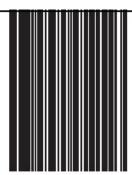


1 bottle inside actual size



**GLUTEN FREE** 

3T3D5 EL C9



#### Drug Facts

Active ingredient (in each capsule) Purpose Lansoprazole 15 mg..... Acid Reducer

- treats frequent heartburn (occurs 2 or more 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 a prescription drug. Acid reducers may interact with certain prescription drugs.

#### Drug Facts (continued)

#### Stop use and ask a doctor if

- vour 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 you develop a rash or joint pain

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

#### 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

#### 14-Day Course of Treatment

- 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

#### Repeated 14-Day Courses (if needed)

- 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
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

#### Drug Facts (continued)

#### Other information

- read the directions and warnings
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and
- protect product from moisture
- close cap tightly after use

#### Inactive ingredients

D&C red no. 28, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, gelatin, hypromellose, low substituted hydroxypropyl cellulose, mannitol, meglumine, methacrylic acid copolymer, pharmaceutical ink, polyethylene glycol, polysorbate 80, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide

Questions or comments? 1-855-423-2630

> KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION.

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING OR BLACK BAND AROUND THE CENTER OF EACH CAPSULE IS MISSING OR BROKEN.



# **EQUALINE LANSOPRAZOLE**

lansoprazole capsule, delayed release

#### **Product Information**

**Product Type HUMAN OTC DRUG** Item Code (Source) NDC:41163-150

**Route of Administration ORAL** 

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
LANSOPRAZOLE (UNII: 0K5C5T2QPG) (LANSOPRAZOLE - UNII:0K5C5T2QPG)	LANSOPRAZOLE	15 mg

Inactive Ingredients		
Ingredient Name	Strength	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)		
MANNITOL (UNII: 30WL53L36A)		
MEGLUMINE (UNII: 6HG8UB2MUY)		
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics				
Color	PINK, GREEN	Score	no score	
Shape	CAPSULE	Size	15mm	
Flavor		Imprint Code	24HR	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41163-150- 01	1 in 1 CARTON	09/02/2021		
1		14 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:41163-150- 03	3 in 1 CARTON	09/28/2021		
2		14 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202319	09/02/2021	

# Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Revised: 6/2023 United Natural Foods, Inc. dba UNFI