# **EQUALINE OMEPRAZOLE-** omeprazole tablet, orally disintegrating, delayed release

United Natural Foods, Inc. dba UNFI

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SuperValu Inc. Omeprazole Drug Facts

### **Active ingredient (in each tablet)**

Omeprazole 20 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 omeprazole.
- omeprazole may cause severe skin reactions. Symptoms may include:
  - skin reddening
  - blisters
  - rash

If an allergic reaction occurs, stop use and seek medical help right away.

# Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain

These may be signs of a serious condition. See your doctor.

# Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- 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 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**

- for 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; some people get complete relief of symptoms within 24 hours

# 14-Day Course of Treatment

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not take this medicine with alcohol

# Repeated 14-Day Course (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 moisture
- take the tablet immediately after opening individual blister. Do not store the tablet outside the blister pack for future use.

#### Inactive ingredients

amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

#### Questions or comments?

1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST

### Package/Label Principal Display Panel

compare to Prilosec OTC®

**EQUALINE**®

MELTech®

Melts In Your Mouth

24 HR

omeprazole

delayed release

orally disintegrating tablets 20mg

acid reducer

dissolve tabs

melts in your mouth

dissolves without water

treats frequent heartburn!

actual size

14 tablets

ONE 14-DAY COURSE OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

strawberry flavor





\*This product is not manufactured or distributed by the owner of the registered trademark Prilosec OTC®.

Safety Feature -Do not use if printed tablet blister unit is open or torn.

MELTech<sup>e</sup>

Melts In Your Mouth

NDC 41163-634-74

compare to Prilosec OTC®

# **EQUALINE®**

# omeprazole

delayed release orally disintegrating tablets 20mg acid reducer

dissolve tabs melts in your mouth dissolves without water treats frequent heartburn!

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Ac tiv e ingre dient (in each table t)

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■ you need to take more than 1 course of treatmentevery 4 months ■ you devel op a rash or jointpain

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#### Drug Facts (continued)

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Que sti ons or comments? 1-800-719-92 60: weekdays 7:30 AM to 5:00 PM EST

Like it or let us make it right.

That's our quality promise.
855-423-2630

Distributed by UNFI Providence, RI 02908 US/ MADE IN ISRAEL

# **EQUALINE OMEPRAZOLE**

omeprazole tablet, orally disintegrating, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-634
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII: KG60484QX9)	OMEPRAZ OLE	20 mg		

Inactive Ingredients	
Ingredient Name	Strength
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 30WL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics				
Color	RED (reddish)	Score	no score	
Shape	ROUND	Size	9mm	
Flavor	STRAWBERRY	Imprint Code	20	
Contains				

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-634- 74	14 in 1 CARTON	10/11/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA209400	10/11/2018	

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

Revised: 8/2023 United Natural Foods, Inc. dba UNFI