GOOD SENSE OMEPRAZOLE- omeprazole tablet, delayed release L. Perrigo Company

Perrigo Omeprazole Delayed Release Tablets 20 mg Drug Facts

Active ingredient (in each tablet)

Omeprazole 20 mg

Purpose

Acid reducer

Use

- 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 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 pain 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

- swallow 1 tablet with a glass of water before eating in the morning
- 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
- swallow whole. Do not chew, crush, or suck tablets.

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. 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) and protect from moisture

Inactive ingredients

benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine, polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, sucralose, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

GOODSENSE_®

FDA APPROVED

Treats Frequent Heartburn!

24 HR

Omeprazole Delayed Release Tablets 20 mg

Acid Reducer

20

Wildberry Mint Coated Tablet

Compare to Prilosec OTC®

Actual Size

SWALLOW - DO NOT CHEW

42 Tablets

Three 14-Day Courses of Treatment

May Take 1 to 4 Days For Full Effect

3 Bottles Inside

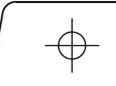


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Delayed Release Tablets 20 mg Acid Reducer

SAFETY FEATURE - DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING.





NDC 0113-1723-03

FDA APPROVED





Treats Frequent Heartburn!

Delayed Release Tablets 20 mg **Acid Reducer**



42 Tablets

Compare to Prilosec OTC®*

Three 14-Day Courses of Treatment May Take 1 to 4 Days For Full Effect

SWALLOW - DO NOT CHEW



Treats Frequent Heartburn!

Delayed Release Tablets 20 mg **Acid Reducer**



Mint Coated Compare to

Actual Size SWALLOW - DO NOT CHEW



Treats Frequent Heartburn!

Delayed Release Tablets 20 mg **Acid Reducer**



Wildberry Mint Coated Compare to Prilosec OTC®* Tablet

Actual Size SWALLOW - DO NOT CHEW

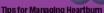
3 Bottles Inside



Delayed Release Tablets 20 mg

Acid Reducer

Wildberry Mint Coated Tablet



- Tips for Managing Heartburn
 Do not lie flat or bend over after eating
 Do not wear tight-fitting clothing around the stomach

- the stomach

 Do not eat before bedtime

 Raise the head of your bed

 Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, aicohol and certain fruits and vegetables

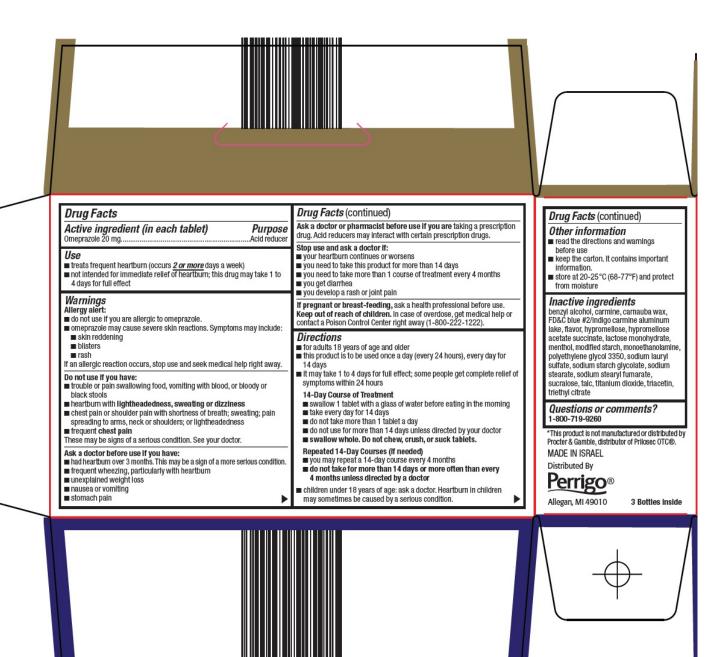
 Eat slowly and avoid big meals

 If overweight, lose weight

 Quit smoking



401D7 C2 C3



GOOD SENSE OMEPRAZOLE

omeprazole tablet, delayed release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-1723	
Route of Administration	ORAL			

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

mactive marealents	Inactive	Ingredients
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Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYPROMELLOSE ACETATE SUCCINATE, UNSPECIFIED (UNII: A7ZHS2RJ34)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics				
Color	PURPLE	Score	no score	
Shape	OVAL	Size	12mm	
Flavor	BERRY	Imprint Code	20	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0113-1723- 03	3 in 1 CARTON	05/22/2019			
1		14 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:0113-1723- 01	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2019			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA022032	05/22/2019		

Labeler - L. Perrigo Company (006013346)

Revised: 3/2024 L. Perrigo Company