FOSTER AND THRIVE OMEPRAZOLE- omeprazole tablet, delayed release Strategic Sourcing Services LLC

McKesson 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 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?

Call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

Package/Label Principal Display Panel

Foster & Thrive™

COMPARE TO PRILOSEC OTC®

Omeprazole Delayed Release Tablets 20 mg

Wildberry Mint Coated Tablet

ACID REDUCER

ACTUAL SIZE

Treats Frequent Heartburn!

24 HR | SWALLOW - DO NOT CHEW

THREE 14-DAY COURSES OF TREATMENT MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

3 Bottles - 14 Tablets each

TOTAL 42 TABLETS



Delayed Release Tablets 20 mg | ACID REDUCER

NDC 70677-1275-1 Foster & Thrive™













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Tips for Managing Heartburn
■ Do not lie flat or bend over after eating
■ Do not wear tight-fitting clothing around 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, alcohol and

certain fruits and vegetables ■ Eat slowly and avoid big meals ■ If overweight, lose weight ■ Quit smoking

Product of Israel

Rev. 09/24



401D7 KM C1



Drug Facts

4 days for full effect

skin reddening ■ blisters

Do not use if you have:

frequent chest pain

■ unexplained weight loss ■ nausea or vomiting

stomach pain

black stools

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■ chest pain or shoulder pain with shortness of breath; sweating; pain

Ask a doctor before use if you have:

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

spreading to arms, neck or shoulders; or lightheadedness

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

■ frequent wheezing, particularly with heartburn

Purpose .Acid reducer

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:

Drug Facts (continued)

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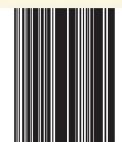
benzyl alcohol, carmine, carnauba wax, FD&C blue #2/indigo carmine aluminum lake, flavor, hypromellose, hypromellose acetate succinate, lactose monohydrate, menthol, modified starch, monoethanolamine polyethylene glycol 3350, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl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

Questions or comments? Call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

Safety Feature - Do not use if printed seal under cap is broken or missing.

3 Bottles inside



FOSTER AND THRIVE OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-1275

ORAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
l	OMEPRAZOLE (UNII: KG604840X9) (OMEPRAZOLE - UNII: KG604840X9)	OMEPRAZ OLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARMINIC ACID (UNII: CID8Z8N95N)	
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:70677- 1275-1	3 in 1 CARTON	11/20/2024			
1	NDC:70677- 1275-2	14 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing I	nformation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022032	11/20/2024	

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 11/2024