

TOPCARE OMEPRAZOLE- omeprazole tablet, delayed release
Topco Associates LLC

Topco Associates LLC. 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

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 or crush 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

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare® health

COMPARE TO PRILOSEC OTC®

Omeprazole

DELAYED RELEASE TABLETS 20 mg

ACID REDUCER

24 HR

Treats Frequent Heartburn!

42 TABLETS

actual size

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

TopCare
health

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

Omeprazole

DELAYED RELEASE TABLETS 20 mg
ACID REDUCER



TopCare
health

NDC 36800-915-55

COMPARE TO
PRILOSEC OTC®*

Omeprazole

DELAYED RELEASE TABLETS 20 mg
ACID REDUCER



Treats Frequent
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42 TABLETS

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

actual
size



91309 88 C10

CODE AREA

Drug Facts**Active Ingredient (in each tablet)** *Purpose*
Omeprazole 20 mg *Add 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

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
 - heartburn with light-headedness, sweating or dizziness
 - chest pain or shoulder pain with hotness 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:

- hot 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 for plan medication use if you are taking a prescription drug. Add reducer may interact with certain prescription drugs.

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get a hives
- you develop a rash or joint pain

Drug Facts (continued)

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
- if you take 1 to 4 days for full effect, some people get complete relief of symptoms within 2-4 hours

14-Day Course of Treatment

- swallow 1 tablet with 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 or crush tablets.

Repeat 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 than every 4 months unless directed by 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

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, hydroxypropylcellulose, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-888-423-0139**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
- Finish 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



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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topcare@topco.com www.topcarebrand.com

MADE IN ISRAEL



Scan here for more information or call 1-888-423-0139

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

DELATED RELEASE TABLETS 20 mg
ACID REDUCER
Omeprazole

TopCare®
health

TOPCARE OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-915
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3W0)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	BROWN	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-915-74	14 in 1 CARTON	02/29/2008	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-915-30	2 in 1 CARTON	02/29/2008	
2		14 in 1 CARTON		
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:36800-915-55	3 in 1 CARTON	02/29/2008	
3		14 in 1 CARTON		
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:36800-915-03	3 in 1 CARTON	12/28/2011	
4		14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:36800-915-01	1 in 1 CARTON	10/11/2010	
5		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
NDA	NDA022032	02/29/2008	

Labeler - Topco Associates LLC (006935977)