

TOPCARE OMEPRAZOLE- omeprazole tablet, orally disintegrating, delayed release

Topco Associates LLC

Topco Associates LLC. Omeprazole 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 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

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

TopCare® health

COMPARE TO PRILOSEC OTC®

MELTech™

Melts In Your Mouth

MELTS IN YOUR MOUTH; DISSOLVES WITHOUT WATER

Omeprazole

DELAYED RELEASE ORALLY DISINTEGRATING TABLETS 20 mg

ACID REDUCER

24 HR

Treats Frequent Heartburn!

STRAWBERRY FLAVOR

14 TABLETS

actual size

ONE 14-DAY COURSE OF TREATMENT • MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT


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

DISTRIBUTED BY TOPCO ASSOCIATES LLC
 ELK GROVE VILLAGE, IL 60007
 ©TOPCO PERAP021 QUESTIONS? 1-888-423-0139
 topcar@topco.com www.topcarandr.com
 MADE IN ISRAEL

Visit here for more information:
<http://topbrnds.com/4900dq>

Drug Facts	Questions or comments?
<p>Drug Facts (continued)</p> <p>Directions ■ for adults 18 years of age and older ■ take 1 tablet before eating in the morning</p> <p>■ do not crush or chew tablets</p> <p>■ place the tablet on tongue; do not swallow with water. The tablet can also be swallowed whole with water.</p> <p>■ take every day for 14 days</p> <p>■ do not take more than 1 tablet a day</p> <p>■ do not use for more than 14 days unless directed by your doctor</p> <p>■ do not take the strawberry with alcohol</p> <p>Repeated 14-Day Course (if needed)</p> <p>■ you may repeat at 4-day course every 4 months</p> <p>■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>■ children under 18 years of age: ask doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information ■ read the directions and warnings before use</p> <p>■ keep the carton tightly closed. Keep product out of high heat and moisture</p> <p>■ store at 20°-25°C (68°-77°F); keep product out of high heat and moisture.</p>	<p>Drug Facts (continued)</p> <p>Warnings</p> <p>■ Allergy alert: do not use if you are allergic to omeprazole</p> <p>Do not use if you have:</p> <ul style="list-style-type: none"> ■ trouble or pain swallowing food, vomiting with blood or bloody or black stools ■ heartburn with light-headedness, sweating or dizziness ■ chest or shoulder pain with shortness of breath; swelling; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ had heartburn for 3 months. This may be a sign of a more serious condition. ■ frequent wheezing, particularly with heartburn ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.</p> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> ■ 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 dizziness ■ you develop a rash or joint pain <p>If pregnant or breastfeeding, ask a health professional before use.</p> <p>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).</p>
<p>Purpose</p> <p>Omeprazole 20 mg ... Acid reducer</p> <p>Actve ingredient (in each tablet)</p>	<p>Questions or comments?</p> <p>5:00 PM EST 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST</p>



0 39800 447575 8

QUALITY GUARANTEED

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

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



NDC 36800-601-74
**COMPARE TO
 PRILOSEC OTC®***



MELTS IN YOUR MOUTH ; DISSOLVES WITHOUT WATER

Omeprazole

DELAYED RELEASE ORALLY DISINTEGRATING TABLETS 20 mg

ACID REDUCER



**Treats Frequent
 Heartburn!**

STRAWBERRY
 FLAVOR



14 TABLETS

actual
 size



Omeprazole
 1Y074 88 C-5

ONE 14-DAY COURSE OF TREATMENT • MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT



TOPCARE OMEPRAZOLE

omeprazole tablet, orally disintegrating, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-601
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
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 3OWL53L36A)	
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:36800-601-74	14 in 1 CARTON	04/02/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-601-55	3 in 1 CARTON	04/02/2018	
2		14 in 1 CARTON		
2		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	04/02/2018	

Labeler - Topco Associates LLC (006935977)

Revised: 4/2022

Topco Associates LLC