

**PRILOSEC OTC- omeprazole magnesium tablet, delayed release**  
**The Procter & Gamble Manufacturing Company**

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**Prilosec OTC®**  
**WILDBERRY**

***Drug Facts***

**Active ingredient (in each tablet)**

Omeprazole delayed-release tablet 20 mg (equivalent to 20.6 mg omeprazole magnesium)

**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.

## **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**

FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, flavor, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, mica, microcrystalline cellulose, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, saccharin sodium, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

## **Questions?**

**1-800-289-9181**

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

**Dist. by Procter & Gamble,  
Cincinnati, OH 45202**

**Product of Sweden**

**PRINCIPAL DISPLAY PANEL - 14 Tablet Carton**

**See current Drug Facts NDC 37000-459-02**

**Treats FREQUENT Heartburn! 24 HR**

**Prilosec OTC ®**

omeprazole delayed-release tablets

20 mg / acid reducer

**SWALLOW - DO NOT CHEW**

**14 TABLETS**

One 14-day course of treatment

May take 1 to 4 days for full effect

WILDBERRY Coated Tablet

**Drug Facts** (continued)

**Drug Facts**

**Active ingredient (in each tablet)**  
**Purpose**  
 Omeprazole delayed-release tablet 20 mg (equivalent to 20.6 mg omeprazole magnesium) ..... Acid reducer

**Use**  
 • treats frequent heartburn (occurs 2 or more days a week) for 1 to 4 days for full effect  
 • not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**Warnings**  
**Allerg alerts:** 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 high blood pressure, 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  
 • frequent wheezing, particularly with heartburn  
 • unexplained weight loss • nausea or vomiting • stomach pain

**Ask a doctor before use if you have:**  
 • had heartburn over 3 months. This may be a sign of a more serious condition.  
 • frequent heartburn with heartburn • nausea or vomiting

**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 more than 14 days  
 • you need to take more than 1 course of treatment  
 • you develop a rash or joint pain  
 • you get diarrhea

**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.**

**Questions? 1-800-289-9181**

**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

**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 often than every 4 months unless directed by a doctor

**Other information**  
 • children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

**Inactive ingredients** FD&C Blue No. 2 aluminum lake, FD&C red no. 40 aluminum lake, flavor, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methylcellulose, copolymer, croscarmellose, polyethylene glycol 6000, polyacrylate, polyvinylpyrrolidone, saccharin sodium, sodium stearate, fumarate, starch, titanium dioxide, triethyl citrate



**P&G**  
 www.pg.com  
 Patents: www.pg.com/patents

NDC 37000-459-02

Treats **FREQUENT** Heartburn!

**24 HR**

# Prilosec

omeprazole delayed-release tablets **OTC**<sup>®</sup>  
 20 mg / acid reducer

**14 TABLETS** **SWALLOW - DO NOT CHEW**

One 14-day course of treatment  
 May take 1 to 4 days for full effect

**WILDBERRY** Coated Tablet



If you are not satisfied with Prilosec OTC,<sup>®</sup> simply return the UPC Code from this package and original sales receipt within 60 days of purchase for a full refund. For offer details, visit PrilosecOTCGuarantee.com.

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

**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

Dist. by Procter & Gamble,  
 Cincinnati, OH 45202  
 Product of Sweden  
 91443618



# PRILOSEC OTC

omeprazole magnesium tablet, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37000-459
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OMEPRAZOLE MAGNESIUM</b> (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, RICE</b> (UNII: 4DGK8B7I3S)	
<b>POVIDONE K60</b> (UNII: SZR7Z3Q2YH)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>FD&amp;C BLUE NO. 2--ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)</b> (UNII: 74G4R6TH13)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</b> (UNII: RFW2ET671P)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	purple	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	P
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:37000-459-01	1 in 1 POUCH; Type 0: Not a Combination Product	08/15/2012	
2	NDC:37000-459-02	14 in 1 CARTON	08/15/2012	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:37000-459-03	2 in 1 CARTON	08/15/2012	12/01/2022
3		14 in 1 CARTON		
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:37000-459-04	3 in 1 CARTON	08/15/2012	
4		14 in 1 CARTON		
4		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:37000-459-05	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/15/2012	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021229	08/15/2012	

**Labeler** - The Procter & Gamble Manufacturing Company (004238200)

**Registrant** - AstraZeneca AB (Sweden) (876516568)

Revised: 10/2025

The Procter & Gamble Manufacturing Company