

**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

<b>Drug Facts</b> (continued)	<b>Drug Facts</b>
<b>Directions</b> • 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	<b>Warnings</b> • Do not use if you are allergic to omeprazole • Ask a doctor before use if you have: • frequent 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
<b>Other information</b> • 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	<b>Ask a doctor or pharmacist before use if you are taking a prescription drug.</b> Acid reducers may interact with certain prescription drugs.
<b>Inactive ingredients</b> FD&C Blue No. 2, aluminum lake, FD&C red no. 40, aluminum lake, flavor, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methylcellulose, polyethylene glycol 6000, polyvinylpyrrolidone, saccharin sodium, sodium lauryl sulfate, starch, sucrose, talc, titanium dioxide, triethyl citrate	<b>Stop use and ask a doctor if:</b> • 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 • you get diarrhea • you develop a rash or joint pain
<b>Questions?</b> 1-800-289-9181	<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.



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

If you are not satisfied with Prilosec OTC, 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.

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

**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				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-459	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)		OMEPRAZOLE	20 mg	
Inactive Ingredients				
Ingredient Name			Strength	
STARCH, RICE (UNII: 4DGK8B7I3S)				
POVIDONE K60 (UNII: SZR7Z3Q2YH)				
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICA (UNII: V8A1AW0880)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)				
SUCROSE (UNII: C151H8M554)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
Product Characteristics				
Color	purple	Score	no score	
Shape	OVAL	Size	15mm	
Flavor	BERRY	Imprint Code	P	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

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: 8/2023

The Procter & Gamble Manufacturing Company