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

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 shoulderpain 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

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Acid reducers may interact with certain prescription drugs.

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Drug Facts (continued)

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Prilosec OTC

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

NDC 37000-459-02

Treats **FREQUENT** Heartburn!

24 HR

Prilosec

omeprazole delayed-release tablets
20 mg / acid reducer

OTC®

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

SWALLOW – DO NOT CHEW

WILDBERRY Coated Tablet

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.

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

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)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
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)	

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: 10/2024 The Procter & Gamble Manufacturing Company