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

-----

### Prilosec OTC<sup>®</sup>

omeprazole magnesium delayed-release tablets 20 mg / acid reducer

### **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 <u>2 or more</u> 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 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

glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium

stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, 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 37000-455-03

### Treats FREQUENT Heartburn! 24 HR

Prilosec**OTC**®

omeprazole delayed-release tablets

20 mg / acid reducer

### **28 TABLETS**

Two 14-day courses of treatment

May take 1 to 4 days for full effect

• read the electors and warmings before use events of the end on a warmings before use events of the end on it contains important information. • skep the end on a warmings before the matter provide the end of t	you get diarrive a very ond to make any ond to make a very ond to make a very ond to make a very of the m
• It may shear p of days to full affect complete relief of symptoms within 24 hours • children may sometimes be caused by a serious condition. • children may sometimes be caused by a serious condition. • children may sometimes be caused by a serious often fiban • con tot take for more than 1 d days or more often fiban • con tot take for more than 1 d days or more often fiban • con tot take for more than 1 d days or more often fiban • con tot take for more than 1 d days or more often fiban • con tot take for more than 1 d days or more often fiban • con tot take for more than 1 d days or more often fiban • con tot take for more than 1 d days or more often fiban • con tot take for more than 1 d days or more often fiban • con tot take fiban 1 days • con take fiban 1 days • con tot take fiban 1 days or more event • con tot take fiban 1 days • con take 1 days •	Allergy aref: - Do not use if you are allergic to omeprazole. - Or not use if you are allergic to comeprazole. - Or not use if you are allergic reschons. Symptoms may include: - Sim reddening - bilsterer rash - froubie or pain evallowing tood, yomiting with blood, or bloody or black stools - receist pain or shoulder pain with shortness of histafts. - frequent chase from increase for allowing tood, or bloody or black stools - frequent chase from increase of which shortness of histafts. - frequent chase from increase of whole for or lightfreadedness - frequent chase from increase of whole for a for allowing to - frequent chase from increase of whole for a form - frequent chase from increase of whole form and a form - frequent chase from increase of whole form and a form of the sign of a more - frequent chase from one of a more a sign of a more - frequent chase from one of a more a sign of a more - frequent chase from one of a more a sign of a more - frequent chase from one of a more a sign of a more - frequent chase from one of a more a sign of a more - frequent chase from one of a more a sign of a more - frequent chase from one of a more a sign of a more - frequent chase from one of a more a sign of a more - from over 3 more of a more a sign of a more - from over 3 more of a sign of a more - from over 3 more of a more and a sign of a more - from over 3 more of a more and a sign of a more - from over 3 more of a more and a sign of a more - from over 3 more of a more and a more and a more and a sign of a more - from over 3 more of a more and a more and a sign of a more and a sign of a more and a sign of a more - from over 3 more o
or contacts a poison Control Center right away. - bits product is to be used once a day (every 24 hours), every day - for adults 18 be used once a day (every 24 hours), every day Directions - for 14 days	(equivalent to 20.6 mg onepracole magnesium) Kcid reducet (equivalent to 20.6 mg onepracole anginesimm) Kcid reducet <b>Vse</b> v for the act frequent has rearburn; this drug may on the rade of to it days for full effect rader 1 of a days for full effect
Drug Facts (continued) If pregnant or breast-feeding, ask a health professional before use. Keep our of reach of children, in case to loverdose, get medical help or context a point for form of neurol control control context and the and or context a point form of neurol control context and taxes.	Drug Facts Active ingredient (in each toblet) Parprasole debyed-release tablet 20 mg

譅







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.

35906

7

37000'

0

**Pegg** www.pg.com Patents: www.pg.com/patents

# Do not wear tight-futting coming around the stomach Do not eat before bedtime Raise the head of your bed Raise the hearburn-causing foods such as rich, spicy, Avoid hearburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables Lowerweight, lose weight Quit smoking

PRILOSEC OTC

blet, delayed	release				
HUMAN OTC	DRUG I	tem Code (Sourc	e)	NDC:3700	0-455
ORAL					
ve Moietv					
Ingredient Name Basis o					Strength
JNII: 426QFE7XL	K) (OMEPRAZ OLE	-			20.6 mg
					20.0 mg
Ingredie	ent Name			Sti	ength
I3S)					
Q2YH)					
E (UNII: RFW2ET6	571P)				
29V3WO)					
9F3G675)					
70097M6I30)					
LINE (UNII: OP1F	R32D61U)				
<b>0</b> (UNII: 30IQX73	30WE)				
239ZG8H)					
. (UNII: 7CV7WJK4	4UI)				
UNII: 2300U9XXI	E4)				
X9V2JP)					
6QXD6UM)					
s					
pink	Score		no	o score	
•					
OVAL	Size		1	5mm	
	Size Imprint Code	•	15 P	5mm	
		•		5mm	
		•		5mm	
		•		5mm	
	Imprint Code	Marketir Da	P Ig Start	Market	ing End
OVAL	Imprint Code	Marketir	P Ig Start	Market	-
OVAL	Imprint Code	Marketir Da	P Ig Start	Market	-
	HUMAN OTC ORAL /e Moiety ngredient Na JNII: 426QFE7XLI Ingredie (UNII: 426QFE7XLI (UNII: 8FW2ETC (UNII: 8FW2ETC (UNII: 8FW2ETC (UNII: 8FW2ETC (UNII: 0011 (UNII: 0011 (UNII: 0011 (UNII: 0010 (UNII: 00	ORAL         ve Moiety         ngredient Name         JNII: 426QFE7XLK) (OMEPRAZ OLE         Ingredient Name         I3S)         Q2YH)         E (UNII: RFW2ET671P)         29V3WO)         PF3G675)         70097M6I30)         LINE (UNII: OP1R32D61U)         0 (UNII: 30IQX730WE)         239Z G8H)         : (UNII: 7CV7WJK4UI)         UNII: 230OU9XXE4)         x9V2JP)         60 XD6UM)	HUMAN OTC DRUG       Item Code (Source         ORAL       Item Code (Source         // C Moiety       Ingredient Name         JNII: 426QFE7XLK) (OMEPRAZ OLE -       Ingredient Name         JNII: 426QFE7XLK) (OMEPRAZ OLE -       Ingredient Name         JS)       Ingredient Name         J2YH)       Ingredient Name         IUNII: RFW2ET671P)       Ingredient Name         29Y3WO)       Ingredient Name         JSS       Ingredient Name         IUNII: RFW2ET671P)       Ingredient Name         29Y3WO)       Ingredient Name         ING (UNII: RFW2ET671P)       Ingredient Name         29Y3WO)       Ingredient Name         ING (UNII: OP1R32D61U)       Ingredient Name         ING (UNII: 30IQX730WE)       Ingredient Name         INGREdient (Ingredient Name)       Ingredient (Ingredient Name)         Ingredient (Ingredient Name)       Ingredient (Ingredient (Ingredient (Ingred	HUMAN OTC DRUG       Item Code (Source)         ORAL       ORAL         ////////////////////////////////////	HUMAN OTC DRUG ORAL       Item Code (Source)       NDC:3700         ORAL       Basis of Strength         ngredient Name       Basis of Strength         JNII: 426QFE7XLK) (OMEPRAZ OLE -       OMEPRAZ OLE -         Ingredient Name       Strength         JNII: 426QFE7XLK) (OMEPRAZ OLE -       OMEPRAZ OLE -         Ingredient Name       Strength         292YH)       Strength         E (UNII: RFW2ET671P)       Strength         293WO)       Strength         JF36675)       Strength         70097M6130)       Ingredient         LINE (UNII: OP1R32D61U)       Ingredient         O (UNII: 30IQX730WE)       Strength         393Z G8H)       Ingredient         I (UNII: 7CV7WJK4UI)       Ingredient         I (UNII: 2300U9XXE4)       Ingredient         X9V2JP)       Ingredient         Strength       Ingredient         I (INII: 2300U9XXE4)       Ingredient         X9V2JP)       Ingredient

		Product		
3	NDC:37000- 455-03	2 in 1 CARTON	07/14/2003	
3		1 in 1 CARTON		
3		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:37000- 455-04	3 in 1 CARTON	07/14/2003	
4		1 in 1 CARTON		
4		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:37000- 455-05	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/14/2003	
M		Information		
M		Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Registrant - AstraZeneca AB (Sweden) (876516568)

### **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
Minakem Dunkerque Production		277412599	api manufacture(37000-455)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Dishman Pharmaceuticals and Chemicals Ltd		915628142	api manufacture(37000-455)

### Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Anderson Brecon Inc.		053217022	pack(37000-455)

## Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Sonoco Display and Packaging		129850751	pack(37000-455)

Revised: 8/2023

The Procter & Gamble Manufacturing Company