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

Prilosec

OTC ®

omeprazole magnesium delayed-

release tablets 20.6 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 ***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 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

- warfarin, clopidogrel, or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)

- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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

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

Dist. by Procter & Gamble, Cincinnati, OH 45202

Product of Sweden

PRINCIPAL DISPLAY PANEL - 14 Tablet Carton

NDC 37000-455-02

Prilosec

OTC ®

omeprazole delayed-release tablets

20 mg / acid reducer

14 TABLETS
One 14-day course of treatment

*Treats **FREQUENT** Heartburn!*
*Occurring **2 Or More Days A Week***

PRILOSEC OTC

omeprazole magnesium tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37000-455
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20.6 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	pink	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	P
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-455-01	1 in 1 POUCH; Type 0: Not a Combination Product	07/14/2003	
2	NDC:37000-455-02	1 in 1 CARTON	07/14/2003	
2		14 in 1 BLISTER PACK; Type 0: Not a Combination 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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021229	07/14/2003	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

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