FAMILY WELLNESS OMEPRAZOLE- omeprazole tablet, orally disintegrating, delayed release

Family Dollar Services Inc

Family Dollar Services, Inc. Omeprazole Drug Facts

Active ingredient (in each tablet)

Omeprazole 20 mg

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 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 (1-800-222-1222).

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

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- 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
- do not take this medicine with alcohol

Repeated 14-Day Course (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 before use. 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); keep product out of high heat and moisture

Inactive ingredients

amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, mannitol,

microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST

Package/Label Principal Display Panel

COMPARE TO: PRILOSEC OTC®

24HR Treats FREQUENT Heartburn!

MELTechTM Melts In Your Mouth

Omeprazole

Delayed Release Orally Disintegrating Tablets 20 mg / Acid Reducer

STRAWBERRY FLAVOR

Melts in your mouth

Dissolves without water

Actual Size

ONE 14-DAY COURSE OF TREATMENT

May take 1 to 4 days for full effect

OTC network

100% SATISFACTION GUARANTEED OR YOUR MONEY BACK

14 TABLETS

*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTO®.

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

COMPARE TO: PRILOSEC OTC®*





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Questions or c am ments? 1-800-719-9260: weekdays 7:30 AM to

NOT 100%, SATISFIED? Petum package and unused product within 30 cays to any Family Dollar store for a refund (with receipt) or exchange.

DISTRIBUTED BY: MIDWOOD BRANDS, LLC 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

FAMILY WELLNESS OMEPRAZOLE

omeprazole tablet, orally disintegrating, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-191
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg		

Inactive Ingredients	
Ingredient Name	Strength
DIMETHYLAMINO ETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics					
Color	RED (reddish)	Score	no score		
Shape	ROUND	Size	9 mm		
Flavor	STRAWBERRY	Imprint Code	20		
Contains					

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-191-74	14 in 1 CARTON	03/26/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
M	arketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NΓ)A	NDA209400	03/26/2019	

Labeler - Family Dollar Services Inc (024472631)

Revised: 6/2019 Family Dollar Services Inc