# EQUATE OMEPRAZOLE- omeprazole magnesium capsule, delayed release WALMART INC.

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#### Wal-Mart Omeprazole Drug Facts

#### Active ingredient (in each capsule)

Omeprazole delayed-release capsule 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

#### 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 (1-888-222-1222).

#### 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

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew or crush capsules.

#### **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
- FDA approved dissolution test specifications differ from USP

#### Inactive ingredients

FD&C yellow #6, ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

#### **Questions or comments?**

1-888-287-1915

#### Package/Label Principal Display Panel

3 PACK

THREE 14-DAY COURSES OF TREATMENT

equate<sup>™</sup>

NEW MINI CAPSULES

Treats FREQUENT Heartburn!

Compare to Prilosec OTC<sup>®</sup> active ingredient

MINI CAPSULES

Omeprazole

Delayed-Release Capsules, 20mg

Acid Reducer

• 24 HR

Actual Size

3 Bottles Inside

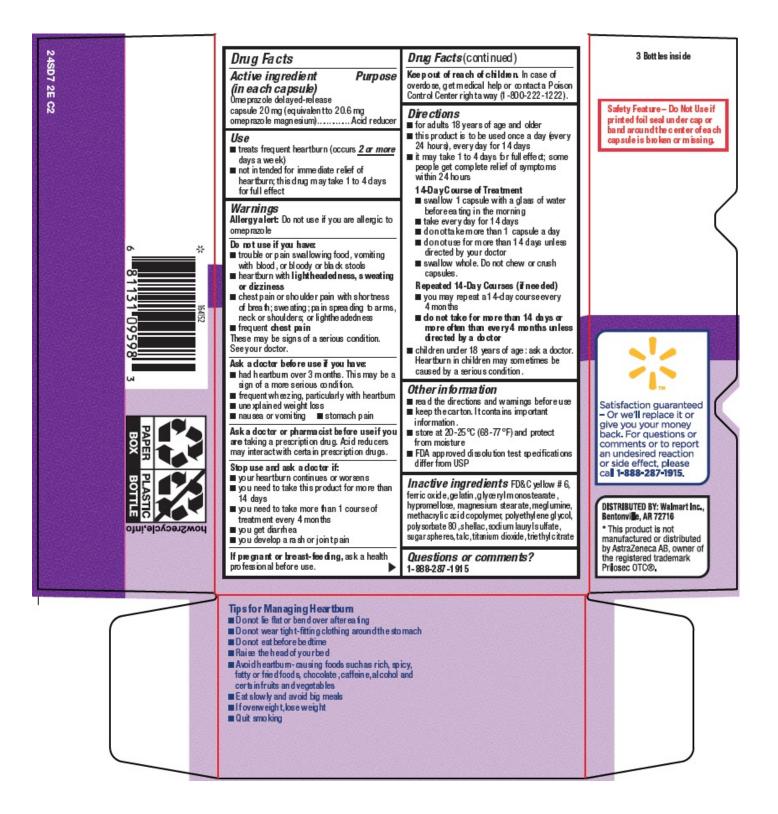
20 mg

42 CAPSULES

Three 14-day courses of treatment

May take 1 to 4 days for full effect





EQUATE OMEPRAZOLE omeprazole magnesium capsule, delayed release				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79903-112	
Route of Administration	ORAL			

Active Ingredient/Ac	line i loiety			
	Ingredient Name		Basis of Strength	Strengt
OMEPRAZOLE MAGNESIUI UNII:KG60484QX9)	(UNII: 426QFE7XLK) (OMEPRAZOLE -		OMEPRAZOLE	20 mg
Inactive Ingredients				
	Ingredient Name			Strength
FD&C YELLOW NO. 6 (UNI	: H77VEI93A8)			
FERRIC OXIDE RED (UNII: 1	K09F3G675)			
GELATIN, UNSPECIFIED (U	NII: 2G86QN327L)			
GLYCERYL MONOSTEARA	<b>E</b> (UNII: 2300U9XXE4)			
HYPROMELLOSE, UNSPEC	IFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (U	NII: 70097M6I30)			
MEGLUMINE (UNII: 6HG8UB	2MUY)			
METHACRYLIC ACID - MET	HYL METHACRYLATE COPOLYMER (1:	<b>L)</b> (UNII: 74G4	R6TH13)	
POLYETHYLENE GLYCOL,	UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYSORBATE 80 (UNII: 60	DZP39ZG8H)			
SHELLAC (UNII: 46N107B71	0)			
SODIUM LAURYL SULFATE	(UNII: 368GB5141J)			
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 1	5FIX9V2JP)			
TRIETHYL CITRATE (UNII: 8	Z96QXD6UM)			

#### **Product Characteristics**

Color	WHITE, ORANGE	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	245
Contains			

#### Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79903-112- 14	1 in 1 CARTON	11/30/2022	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:79903-112- 28	2 in 1 CARTON	11/30/2022	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:79903-112- 42	3 in 1 CARTON	11/30/2022	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216096	11/30/2022	

### Labeler - WALMART INC. (051957769)

Revised: 12/2022

WALMART INC.