QUALITY CHOICE OMEPRAZOLE - omeprazole tablet, delayed release
Chain Drug Marketing Association

Active ingredient (in each tablet)

Omeprazole delayed-release tablet, 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. 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.
- 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**
- 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 (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

S**top 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

- 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, although 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)
- keep product out of high heat and humidity
- protect product from moisture

Inactive ingredients

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments?

Call 1-800-540-3765

Principal Display Panel

NDC 63868-170-42

QUALITY CHOICE

Treats **Frequent** Heartburn!

Occurring **2 or more days a week**

Omeprazole

Delayed Release Tablets, 20mg

Frequent Heartburn Relief

Acid Reducer

42 Tablets

Three 14-day courses of treatment

Drug Facts (continued)

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Questions or Comments? Call 1-800-540-8765

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

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Frequent Heartburn Relief

Omeprazole

Delayed Release Tablets, 20mg | Add Reducer

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QUALITY CHOICE

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Three 14-day courses of treatment

Tablets

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Frequent Heartburn Relief

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QUALITY CHOICE

NDC 63868-170-42

Frequent Heartburn Relief

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QUALITY CHOICE

NDC 63868-170-42

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Stop use and ask a doctor if ■ you get diarrhea

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Drug Facts (continued)

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▼

Tamper Evident-Do not use if printed tablet blister unit is open or torn.

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Novi, MI 48375-5395
www.qualitychoice.com
Questions? 248-449-9300

SATISFACTION GUARANTEED

Made in Israel

QUALITY CHOICE OMEPRAZOLE

omeprazole tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-170
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYPROMELLOSE ACETATE SUCCINATE 12070923 (3 MM2/S) (UNII: 36BGF0E889)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	OVAL (capsule-shaped)	**Size**	13mm
Flavor		**Imprint Code**	20
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63868-170-42	3 in 1 CARTON		

1		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022032	03/01/2014	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 5/2014 Chain Drug Marketing Association