HEALTHY ACCENTS OMEPRAZOLE- omeprazole tablet, delayed release
DZA Brands LLC

DZA Brands, LLC Omeprazole Drug Facts

Active ingredient (in each tablet)

Omeprazole 20 mg

Purpose

Acid reducer

Uses

- 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)

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. (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

- 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

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?

1-866-322-2439

Principal Display Panel

omeprazole

delayed release tablets 20 mg

acid reducer

treats frequent heartburn!

occurring 2 or more days a week

14-day course of treatment {Replace “#” with the number of courses of treatment in the carton}

NDC 55316-915-74

healthy accents®

omeprazole

delayed release tablets 20mg

acid reducer

treats **frequent** heartburn!
occurring **2 or more days a week**

14 tablets
one 14-day course of treatment

DISTRIBUTED BY: DZA BRANDS, LLC
Salisbury, NC 28147 / Scarborough, ME 04074
MADE IN ISRAEL
For product questions or concerns contact us at 1-866-322-2439.
Please include UPC number and code from package.

MONEY BACK • SATISFACTION GUARANTEE •

: 91574 HA C7

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

TreatMyHeartburn.com

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Drug Facts

Active ingredient (in each tablet)	***Purpose***
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Warnings

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Ask a doctor before use if you have
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■ 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

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Drug Facts (continued)

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Questions or comments? **1-866-322-2439**

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

HEALTHY ACCENTS OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:55316-915
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (OMEPRAZOLE)	OMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX	
FERRIC OXIDE RED	
FERRIC OXIDE YELLOW	
HYPROMELLOSES	
LACTOSE MONOHYDRATE	
PROPYLENE GLYCOL	
SODIUM LAURYL SULFATE	
SODIUM STEARATE	
SODIUM STEARYL FUMARATE	
TALC	
TITANIUM DIOXIDE	
TRIETHYL CITRATE	
MONOETHANOLAMINE	

Product Characteristics

Color	BROWN	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-915-55	3 in 1 CARTON		
1		1 in 1 CARTON		
1		14 in 1 BLISTER PACK		

2	NDC:55316-915-74	1 in 1 CARTON		
2		14 in 1 BLISTER PACK		
3	NDC:55316-915-30	2 in 1 CARTON		
3		1 in 1 CARTON		
3		14 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022032	03/03/2008	

Labeler - DZA Brands LLC (090322194)

Revised: 2/2013 DZA Brands LLC