

OMEPRAZOLE- omeprazole tablet, delayed release
Rite Aid Corporation

Rite Aid Corporation Omeprazole Delayed Release Tablets 20 mg 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. 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 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. (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?

1-800-719-9260

Principal Display Panel

3 BOTTLES INSIDE

omeprazole

delayed release tablets 20 mg

acid reducer

TREATS FREQUENT HEARTBURN!

occurring 2 or more days a week

ACTUAL SIZE

42 TABLETS

three 14-day courses of treatment

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



Safety Feature - Do not use if printed seal under cap is broken or missing.

3 BOTTLES INSIDE



omeprazole

delayed release tablets 20 mg

acid reducer

TREATS FREQUENT HEARTBURN!

occurring **2 or more** days a week

ACTUAL SIZE



42 TABLETS

three 14-day courses of treatment



omeprazole

delayed release tablets 20 mg

acid reducer

TREATS FREQUENT HEARTBURN!

occurring **2 or more** days a week

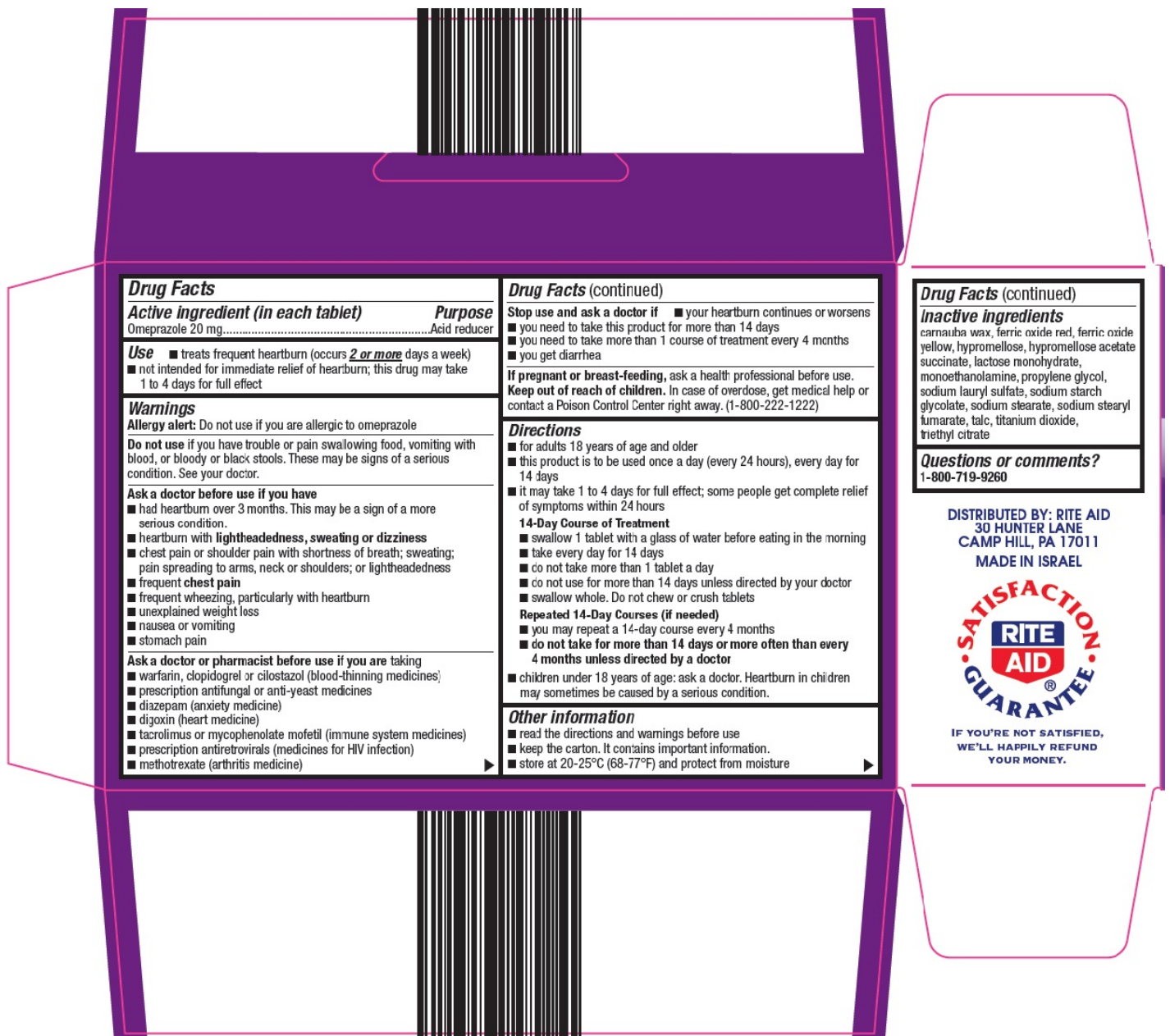
RA# 0357353



LOT NO.

EXP.

: 91507 03 C4



Drug Facts

Active ingredient (in each tablet) **Purpose**
 Omeprazole 20 mg.....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 or mycophenolate mofetil (immune system medicines)
 ■ prescription antiretrovirals (medicines for HIV infection)
 ■ methotrexate (arthritis medicine)

Drug Facts (continued)

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

Drug Facts (continued)

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?

1-800-719-9260

DISTRIBUTED BY: RITE AID
 30 HUNTER LANE
 CAMP HILL, PA 17011
 MADE IN ISRAEL



IF YOU'RE NOT SATISFIED,
 WE'LL HAPPILY REFUND
 YOUR MONEY.

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0915
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)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	

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:11822-0915-2	1 in 1 CARTON		
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-0915-1	2 in 1 CARTON		
2		1 in 1 CARTON		
2		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11822-0915-3	3 in 1 CARTON		
3		1 in 1 CARTON		
3		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:11822-0915-5	1 in 1 CARTON		
4		14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:11822-0915-4	2 in 1 CARTON		
5		14 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:11822-0915-6	3 in 1 CARTON		
6		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
NDA	NDA022032	02/25/2008	

