OMEPRAZOLE- omeprazole tablet, delayed release
Allegiant Health

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476 - Omeprazole Delayed Release Tablet

Active ingredient(s)

Omeprazole Delayed-Release Tablet, 20 mg
(equivalent to 20.6 mg omeprazole magnesium USP)

Purpose

Acid reducer

Use(s)

• 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.
• Omeprazole may cause severe skin reactions. Symptoms may include:
  • skin reddening • blisters • rash
If an allergy reaction occurs, stop use and seek medical help right away.

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 breastfeeding,

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

• 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 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° to 25° C (68° to 77° F) and protect from moisture

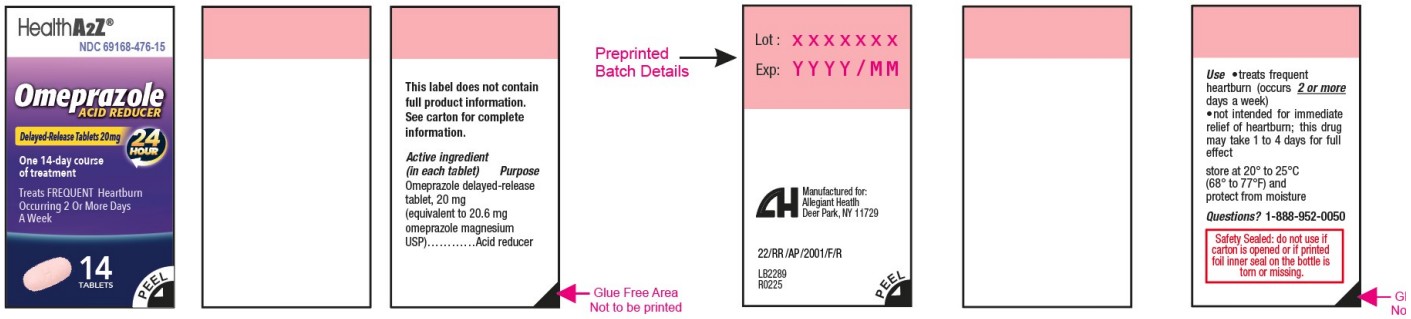
Inactive ingredients

colloidal silicon dioxide, crospovidone, glyceryl monostearate, hypromellose, hydroxypropyl cellulose, iron oxide red, magnesium stearate, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, silicified microcrystalline cellulose, sodium hydroxide, sodium lauryl sulphate, starlac (contains lactose monohydrate and corn starch), sugar spheres (contains sucrose and corn starch), talc, titanium dioxide, triethyl citrate.

Questions/Comments

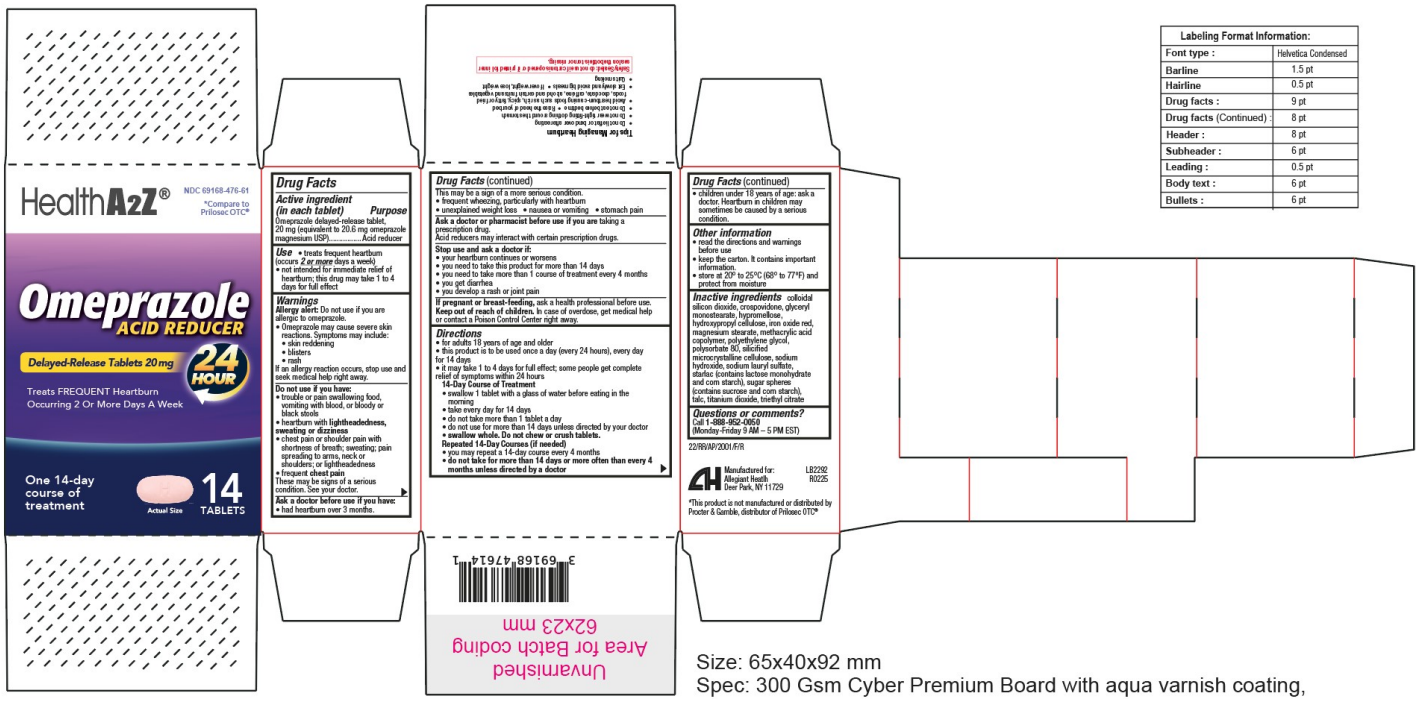
Call **1-888-952-0050**
(Monday-Friday 9 AM – 5 PM EST

Principal Display Panel



Layer 1 (Front) Layer 1 (Back) Layer 2 (Front) Label 2 (front) Label 2 (Front Back) Label 2 (2nd Layer)

Omeprazole label



Size: 65x40x92 mm
Spec: 300 Gsm Cyber Premium Board with aqua varnish coating,

Omeprazole carton

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-476
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID-ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	pink	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	H;O9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-476-14	1 in 1 CARTON	03/21/2025	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-476-42	3 in 1 CARTON	03/21/2025	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69168-476-61	1 in 1 CARTON	03/21/2025	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69168-476-15	14 in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211732	03/21/2025	

Labeler - Allegiant Health (079501930)

Revised: 3/2025 Allegiant Health