

**OMEPRAZOLE- omeprazole capsule, delayed release**  
**Ohm Laboratories Inc.**

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**Omeprazole**

***Drug Facts***

**Active ingredient (in each capsule)**

\*Omeprazole delayed-release capsule 20 mg (equivalent to 20.6 mg omeprazole magnesium, USP)

**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
- 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 **(1-800-222-1222)**.

### **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 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). [See USP controlled room temperature]. Protect from moisture

### **Inactive ingredients**

FD&C blue #1, FD&C red #40, ferrousferrous oxide, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium stearate, methacrylic acid copolymer, mono and di glycerides, polyethylene glycol 6000, polysorbate 80, potassium hydroxide, propylene glycol, shellac, sodium stearyl fumarate, sugar spheres (starch and sucrose), talc, titanium dioxide and triethyl citrate

### **Questions?**

Call toll-free Monday to Friday 8:30 am to 5 pm EST at **1800-406-7984**.

Distributed by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

### **PRINCIPAL DISPLAY PANEL - 20 mg Capsule Bottle Carton**

†Compare To  
the active ingredient of  
Prilosec OTC®

NDC 51660-061-27

2x14 COUNT BOTTLE INSIDE

Treats FREQUENT Heartburn!

24

HR

Omeprazole

Delayed-release Capsules

20 mg\* / Acid Reducer

ohm<sup>®</sup>

28 CAPSULES

Two 14-day courses of treatment

May take 1 to 4 days for full effect

# Omeprazole

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ohm®

### Drug Facts (continued)

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**TAMPER-EVIDENT FEATURES:**  
Do not use if foil seal under cap imprinted with 'sealed for your protection' or transparent band around center of capsule are missing, torn or broken.

### 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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†Ohm® is a registered trademark of Sun Pharmaceutical Industries, Inc.  
All other trademarks are property of their respective owners.

R0419

Distributed by:  
Ohm Laboratories Inc.  
New Brunswick, NJ 08901



Batch No.

Expiration Date:

**NON VARNISH**





5198315

NO COATING

GLUE - NO COATING

**Drug Facts**

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**Inactive ingredients**

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NO COATING



5198315

**OMEPRAZOLE**

omeprazole capsule, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51660-061
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20.6 mg

**Inactive Ingredients**

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 66O7AQV0RT)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	

**Product Characteristics**

Color	PINK	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	RG;49
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-061-44	3 in 1 CARTON	07/21/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51660-061-27	2 in 1 CARTON	07/21/2018	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:51660-061-14	1 in 1 CARTON	07/21/2018	
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
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ANDA	ANDA210593	07/21/2018	
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**Labeler** - Ohm Laboratories Inc. (184769029)

**Registrant** - Ohm Laboratories Inc. (184769029)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Ohm Laboratories Inc.		184769029	MANUFACTURE(51660-061)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Srini Pharmaceuticals Private Limited		725914795	API MANUFACTURE(51660-061)

Revised: 5/2019

Ohm Laboratories Inc.