OMEPRAZOLE- omeprazole capsule, delayed release Ohm Laboratories Inc.

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 <u>2 or more</u> 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, ferrosoferric 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®

28 CAPSULES Two 14-day courses of treatment May take 1 to 4 days for full effect

Omeprazole Delayed-release Capsules 20 mg* / Acid Reducer

[†]Compare To the active Ingredient of Prilosec OTC®

2x14 COUNT BOTTLE INSIDE

Treats FREQUENT Heartburn!

24. HR

ohm

NDC 51660-061-27

Omeprazole Delayed-release Capsules 20 mg* / Acid Reducer

Tips for Mana ging Heartburn Do not lie fat 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, fatly or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables Eat slowly and avoid big meals I overweight, lose weight Quit smoking

Drug Facts (continued) magnesium carbonate, magnesium stearate, methacrylic acid copolymer, mono and di glycerides, polyethylene glycol 6000, polysorbate

triethyl citrate Questions?

EST at 1800-406-7984.

80, potassium hydroxide, propylene glycol, shellac, sodium stearyl fumarate, sugar spheres (starch and sucrose), talc, titanium dioxide and

Call toll-free Monday to Friday 8:30 am to 5 pm

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.

> **28** CAPSULES Two 14-day courses of treatment May take 1 to 4 days for full effect

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

NON VARNISH

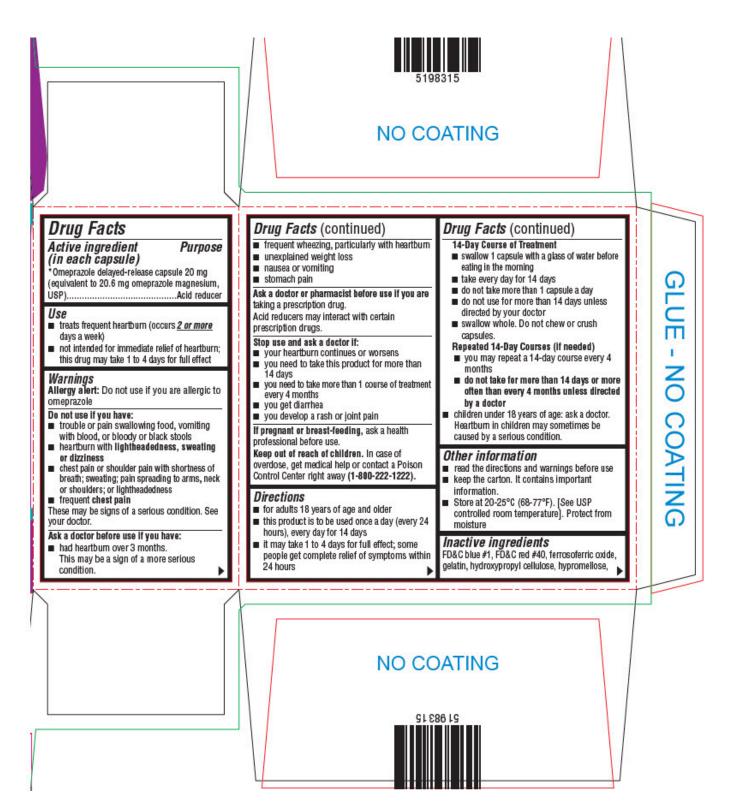
R0419

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



Batch No.

Expiration Date:



OMEPRAZOLE					
omeprazole capsule, delayed relea	se				
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:51660-061		
Route of Administration	ORAL				

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07/21/2018

Labeler - Ohm Laboratories Inc. (184769029)

Registrant - Ohm Laboratories Inc. (184769029)

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

Establishment

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

Revised: 5/2019

Ohm Laboratories Inc.