OMEPRAZOLE- omeprazole tablet, delayed release
OHM LABORATORIES INC.

Omeprazole Delayed-release Tablets, 20 mg

Drug Facts

Active ingredient(in each tablet)

Omeprazole USP 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
- 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 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 to 25° C (68 to 77° F) and protect from moisture

Inactive ingredients

anhydrous lactose, hypromellose, hypromellose acetate succinate, iron oxide red, iron oxide yellow, lactose monohydrate, methyl cellulose, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, triethyl citrate and titanium dioxide.

The imprinting ink contains ammonium hydroxide, black iron oxide, n-butyl alcohol, propylene glycol and shellac.

Questions or Comments?

Call toll free 1-800-818-4555 weekdays.

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

Manufactured by:
Sun Pharmaceutical Industries Limited
Survey No. 259/15, Dadra-396 191,
(U.T. of D & NH), India.

PRINCIPAL DISPLAY PANEL - 20 mg Tablet Bottle Carton

NDC 51660-029-44

†Compare To Prilosec OTC®

Treats FREQUENT Heartburn!

24
HR

Omeprazole Delayed-Release Tablets
20 mg / Acid Reducer

SWALLOW- DO NOT CHEW

ohm®

42 Tablets

THREE 14-DAY COURSES OF TREATMENT
May take 1 to 4 days for full effect

†Compare To Prilosec OTC®

NDC 51660-029-44

Treats **FREQUENT** Heartburn!

24 HR

Omeprazole Delayed-Release Tablets 20 mg / *Acid Reducer*

SWALLOW- DO NOT CHEW

ohm®

†Compare To Prilosec OTC®

NDC 51660-029-44

Treats **FREQUENT** Heartburn!

24 HR

Omeprazole Delayed-Release Tablets 20 mg / *Acid Reducer*

SWALLOW- DO NOT CHEW

ohm®

42 Tablets

THREE 14-DAY COURSES OF TREATMENT

May take 1 to 4 days for full effect

20

ISS.08/2019

N 3 51660 02944 4

PGSB0940A

DNH/DRUGS/NH/138

Drug Facts (continued)

The imprinting ink contains ammonium hydroxide, black iron oxide, n-butyl alcohol, propylene glycol and shellac.

Questions or Comments?

Call toll free 1-800-818-4555 weekdays.

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

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

Manufactured by:
Sun Pharmaceutical Industries Limited
Survey No. 259/15, Dadra-396 191,
(U.T. of D & NH), India.

Drug Facts

Active ingredient (in each tablet)	*Purpose*
Omeprazole USP 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
- 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**

Drug Facts (continued)

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.

Drug Facts (continued)

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

Drug Facts (continued)

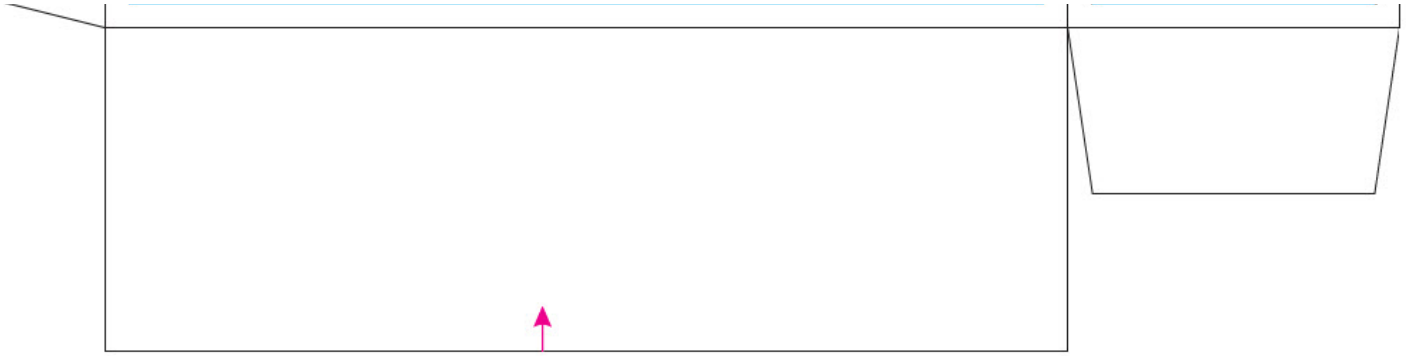
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

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

anhydrous lactose, hypromellose, hypromellose acetate succinate, iron oxide red, iron oxide yellow, lactose monohydrate, methyl cellulose, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, triethyl citrate and titanium dioxide.



OMEPRAZOLE

omeprazole tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-029
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**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYPROMELLOSE ACETATE SUCCINATE 12070923 (3 MM2/S) (UNII: 36BGF0E889)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
METHYLCELLULOSE (1500 MPA.S) (UNII: P0NTE48364)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
AMMONIA (UNII: 5138Q19F1X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics			
Color	BROWN (brownish pink)	**Score**	no score
Shape	OVAL (biconvex)	**Size**	12mm
Flavor		**Imprint Code**	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-029-44	3 in 1 CARTON	06/01/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51660-029-14	1 in 1 CARTON	06/01/2019	
2		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
ANDA	ANDA207891	06/01/2019	

Labeler - OHM LABORATORIES INC. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(51660-029) , MANUFACTURE(51660-029)

Revised: 8/2019 OHM LABORATORIES INC.