OMEPRAZOLE- omeprazole capsule, delayed release
INNOVUS PHARMACEUTICALS, INC.

Drug Facts

Active ingredient(in each capsule)

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

Purpose

Acid reducer

Keep Out of Reach of Children

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.

Otherinformation

- 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 **1-800-818-4555**.

Package/Label Principal Display Panel

NDC 57483-740-42

Compare To the active ingredient of Prilosec OTC®

Treats FREQUENT Heartburn!

OmepraCareDR™

Omeprazole

Delayed-release Capsules 20 mg*

Acid Reducer

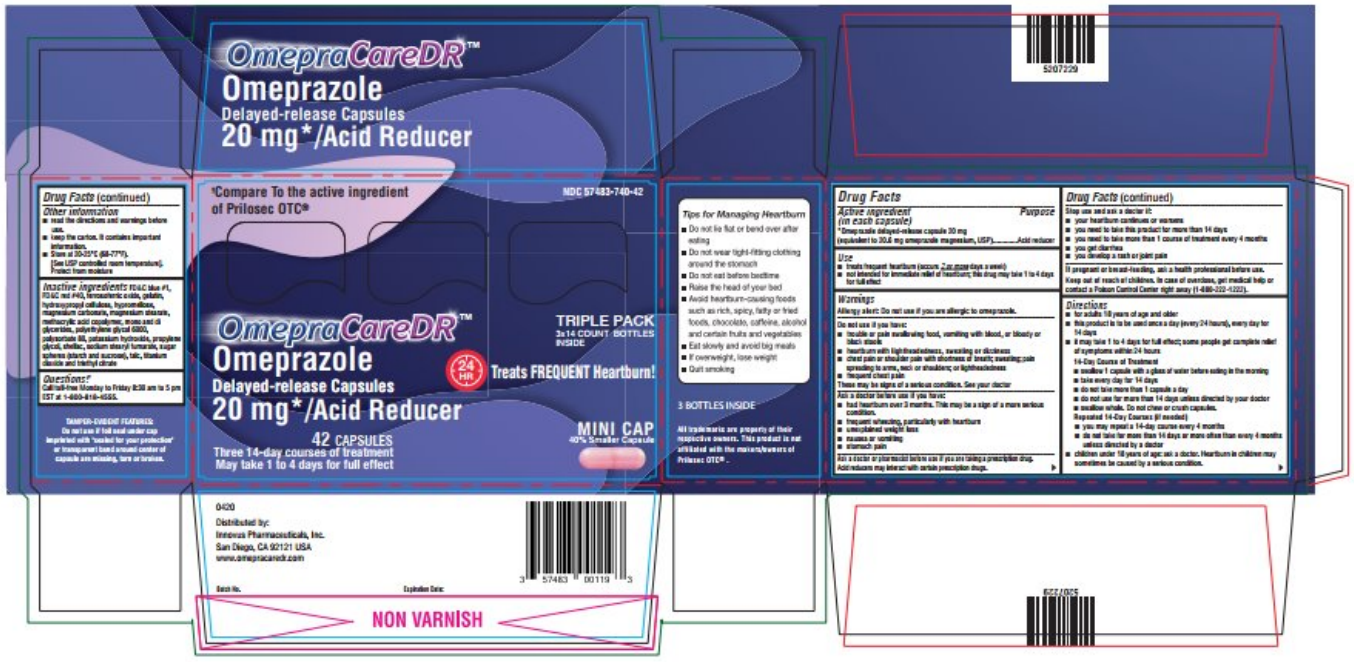
Mini Cap 40% Smaller Capsule

24HR

42 CAPSULES

Three 14-DAY courses of treatment

May take 1 to 4 days for full effect



OMEPRAZOLE

omeprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57483-740
Route of Administration	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
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
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: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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**	RG49
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-740-42	3 in 1 CARTON	08/06/2020	
1	NDC:57483-740-01	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	ANDA210593	08/06/2020	

Labeler - INNOVUS PHARMACEUTICALS, INC. (962507187)

Establishment

Name	Address	ID/FEI	Business Operations

Ohm Laboratories Inc.		184769029	MANUFACTURE(57483-740)

Revised: 8/2020 INNOVUS PHARMACEUTICALS, INC.