

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

Drug Facts

Active ingredient(in each tablet)

Omeprazole USP 20 mg

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.

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.

Package/Label Principal Display Panel

NDC 57483-840-42

Compare To Prilosec OTC®

Treats FREQUENT Heartburn!

OmepraCareDR™

Omeprazole

Delayed-release Tablets 20 mg

Acid Reducer

SWALLOW-DO NOT CHEW

24HR

42 TABLETS

Three 14-DAY courses of treatment

May take 1 to 4 days for full effect

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57483-840
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)	
FERROSFERRIC 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
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1	NDC:57483-840-42	3 in 1 CARTON	08/10/2020	
1	NDC:57483-840-01	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	ANDA207891		08/10/2020	

Labeler - INNOVUS PHARMACEUTICALS, INC. (962507187)

Establishment			
Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	MANUFACTURE(57483-840)

Revised: 8/2020

INNOVUS PHARMACEUTICALS, INC.