ACID REDUCER - omeprazole tablet, delayed release
INNOVUS PHARMACEUTICALS, INC.

Omeprazole Delayed-Release Tablets 20 mg

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

Drug Facts

Active ingredient (in each tablet)

Omeprazole delayed-release tablet 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.
- Omeprazole may cause severe skin reactions. Symptoms may Include:
  - skin reddening • blisters • rash

If an allergic reaction occurs, stop use and seek medical help right way.

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 (1-800-222-1222) right away.

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 20º to 25ºC (68º to 77º F) and protect from moisture

Inactive ingredients

crospovidone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer dispersion, microcrystalline cellulose, polyethylene glycol, polysorbate 80, red iron oxide, silicified microcrystalline cellulose, sodium hydroxide, sodium stearyl fumarate, sugar spheres [which contains liquid glucose, starch (maize) and sucrose], talc, titanium dioxide, triethyl citrate and yellow iron oxide.

Questions?

Call **1-855-274-4122**

Distributed By:
Innovus Pharmaceuticals, Inc.
Englewood, CO 80112
www.crclehealth.com

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Tablet Bottle)

NDC 57483-120-14
C'rcle™ Heartburn Relief
OmepraCareDR®
Omeprazole
Delayed-Release Tablets
20 mg / Acid Reducer

See current
Drug Facts

24
hour
Treats Frequent Heartburn

14 TABLETS
One 14-day course of treatment
May take 1 to 4 days for full effect

Top Ply

NDC 57483-120-14

Circle. **Heartburn Relief**

OmepraCareDR®

Omeprazole

Delayed-Release Tablets

20 mg / Acid Reducer

See current Drug Facts

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One 14-day course of treatment
May take 1 to 4 days for full effect

24 hour Treats Frequent Heartburn

Tips for Managing Heartburn

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- Quit smoking

Distributed By:
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www.crclehealth.com

100710-1 01.23

TAMPER EVIDENT - Do not use if seal over bottle opening is broken or missing.

Made in India
Code: TS/DRUGS/22/2009

P1432346 LM-5096

Lift Here

No Varnish

Top Ply (Page #1)

Active ingredient (in each tablet) ***Purpose***

Omeprazole delayed-release tablet 20 mg (equivalent to 20.6 mg omeprazole magnesium USP) ..... 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. ■ Omeprazole may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If an allergic reaction occurs, stop use and seek medical help right away. **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

P1432346 LM-5096

HINGE

Back of Top Ply (Page #2)

Bottom Ply

HINGE

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 (1-800-222-1222) right away. ***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*** crospovidone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer dispersion, microcrystalline cellulose, polyethylene glycol, polysorbate 80, red iron oxide, silicified microcrystalline cellulose, sodium hydroxide, sodium stearyl fumarate, sugar spheres [which contains liquid glucose, starch (maize) and sucrose], talc, titanium dioxide, triethyl citrate and yellow iron oxide. ***Questions?*** Call **1-855-274-4122**

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Base (Page #3)

Bottom Ply

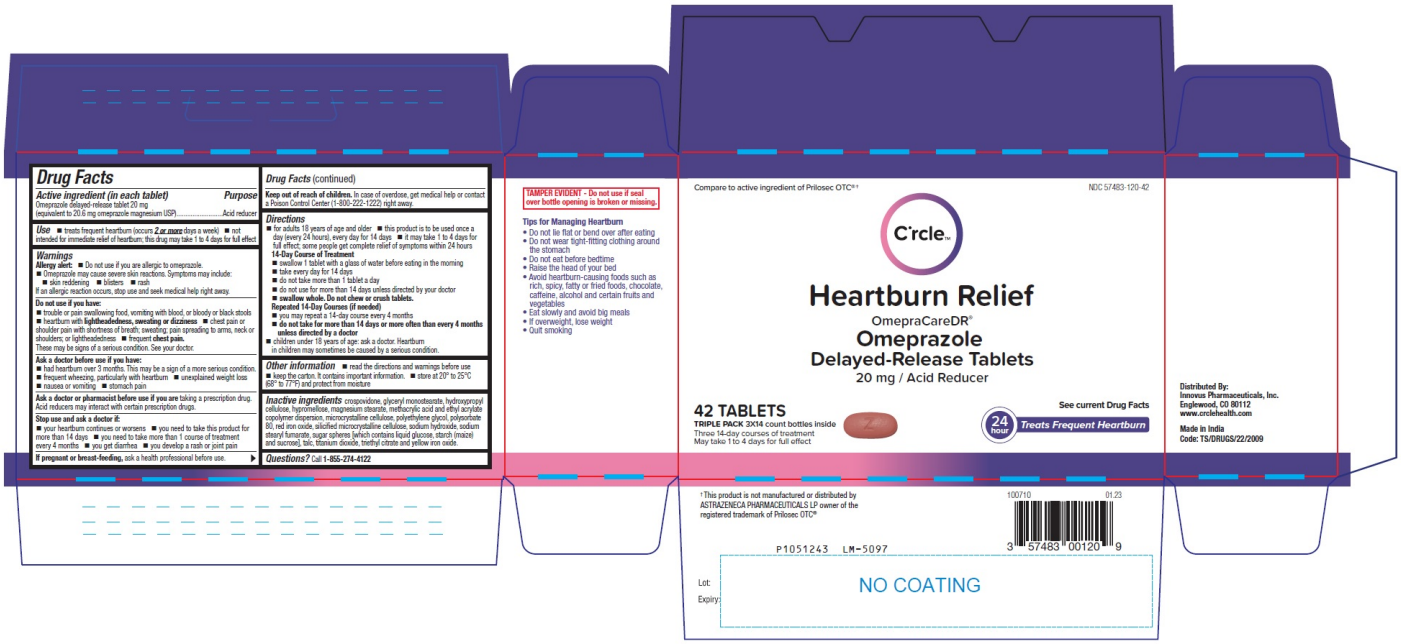
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg Container Carton Label

Compare to active ingredient of Prilsec OTC®* NDC 57483-120-42
C'rcle™
Heartburn Relief
OmepraCareDR®
Omeprazole
Delayed-Release Tablets
20 mg / Acid Reducer

See current Drug Facts

24
hour
Treats Frequent Heartburn

42 TABLETS
TRIPLE PACK 3X14 count bottles inside
Three 14-day course of treatment
May take 1 to 4 days for full effect



ACID REDUCER

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57483-120
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (35 .MU.M) (UNII: 40UAA97IT9)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE (45000 WAMW) (UNII: 8VAB711C5E)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	RECTANGLE (Oblong)	**Size**	14mm
Flavor		**Imprint Code**	Z;69
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-120-42	3 in 1 CARTON	05/25/2023	
1		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	ANDA206877	05/25/2023	

Labeler - INNOVUS PHARMACEUTICALS, INC. (962507187)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(57483-120) , MANUFACTURE(57483-120)

Revised: 5/2023 INNOVUS PHARMACEUTICALS, INC.