

## ACID REDUCER - omeprazole tablet, delayed release Cardinal Health

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### 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

##### 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 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**

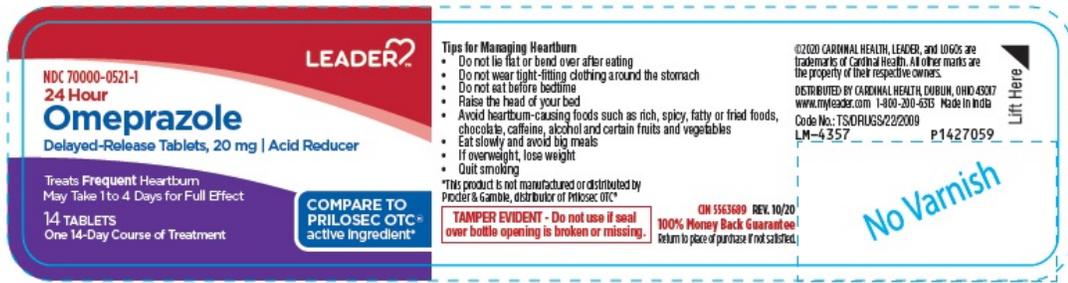
DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-6313

**Essential to Care™ since 1979**

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

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

**LEADER™**  
**NDC 70000-0521-1**  
**24 Hour**  
**Omeprazole**  
**Delayed-Release Tablets, 20 mg | Acid Reducer**  
Treats **Frequent** Heartburn  
May Take 1 to 4 Days for Full Effect  
**COMPARE TO**  
**PRILOSEC OTC®**  
**active ingredient\***  
**14 TABLETS**  
**One 14-Day Course of Treatment**



**Top Ply  
 (Page #1)**

**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. 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

LM-4357

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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** croscopolidone, 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

LM-4357

**Base  
 (Page #3)**

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

**LEADER™**  
**NDC 70000-0521-1**  
**24 Hour**  
**Omeprazole**  
**Delayed-Release Tablets, 20 mg**  
**Acid Reducer**  
**Actual Size**  
 Treats **Frequent** Heartburn  
 May Take 1 to 4 Days  
 for Full Effect

**COMPARE TO  
PRILOSEC OTC®  
active ingredients\*  
100% Money  
Back Guarantee  
14 TABLETS  
One 14-Day Course  
of Treatment**



**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg Blister Carton Label**

**LEADER™  
NDC 70000-0521-2  
24 Hour  
Omeprazole  
Delayed-Release Tablets, 20 mg**

**Acid Reducer**

Treats **Frequent** Heartburn

May Take 1 to 4 Days  
for Full Effect

**COMPARE TO  
PRILOSEC OTC<sup>®</sup>  
active ingredients\***

**100% Money**

**Back Guarantee**

**Actual Size**

**14(1x14) TABLETS**

One 14-Day Course of Treatment

**24 Hour**  
**Omeprazole**  
 Delayed-Release Tablets, 20 mg  
 Acid Reducer

LEADER™

NO. C 20 00 0-0521-2

Treats Frequent Heartburn  
 May Take 1 to 4 Days for Full Effect

14 (1x14) TABLETS  
 One 14-Day Course of Treatment

Adult Size

100% Money Back Guarantee

COMPARE TO PRILLOSEC OTC® active ingredient

Cardinal Health™

1-800-20-0523  
 www.cardinal.com  
 1100 N. High St.  
 Columbus, OH 43215  
 U.S.A.

REV 10/20  
 CIN 5673611  
 9629514033

Co. #: TS/DRUGS/222009

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b>          Omeprazole delayed-release tablet 20 mg (equivalent to 20.6 mg omeprazole magnesium USP).....Acid reducer</p> <p><b>Use</b> ■ 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</p> <p><b>Warnings</b>  <b>Allergy alert:</b> Do not use if you are allergic to omeprazole</p> <p>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.</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.</p> <p>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</p> <p>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.</p> <p><b>Directions</b>          ■ 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</p>	<p><b>Drug Facts (continued)</b></p> <p><b>14-Day Course of Treatment</b>          ■ 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.  <b>Repeated 14-Day Courses (if needed)</b>          ■ 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.</p> <p><b>Other information</b> ■ 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</p> <p><b>Inactive ingredients</b> crospravodone, 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.</p> <p><b>Questions?</b> Call 1-855-274-4122</p> <p><b>Tips for Managing Heartburn</b>          • 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</p>
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No Varnish Area

Lot: XXXXXXXX  
 EXP: MM/YYYY  
 Prefix & Variables of Lot, EXP shall be printed online during packing.

SAFETY FEATURE - Do not use if the blister is damaged.

All LEADER™ Brand products have a 100% Money Back Guarantee.

Return to place of purchase for refund.

This product is not manufactured or distributed by Procter & Gamble the distributor of Prilosec OTC®.

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**ACID REDUCER**  
 omeprazole tablet, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0521
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CROSPROVIDONE (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: 4R4HF16D95)	
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**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0521-1	1 in 1 CARTON	06/06/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0521-3	2 in 1 CARTON	10/21/2020	

2		14 in 1 BOTTLE; Type 0: Not a Combination Product	
3	NDC:70000-0521-4	3 in 1 CARTON	10/21/2020
3		14 in 1 BOTTLE; Type 0: Not a Combination Product	
4	NDC:70000-0521-2	1 in 1 CARTON	10/21/2020
4		14 in 1 BLISTER PACK; Type 0: Not a Combination Product	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206877	06/06/2018	

**Labeler** - Cardinal Health (097537435)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(70000-0521) , MANUFACTURE(70000-0521)

Revised: 10/2020

Cardinal Health