

ACID REDUCER - omeprazole tablet, delayed release

Cardinal Health

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

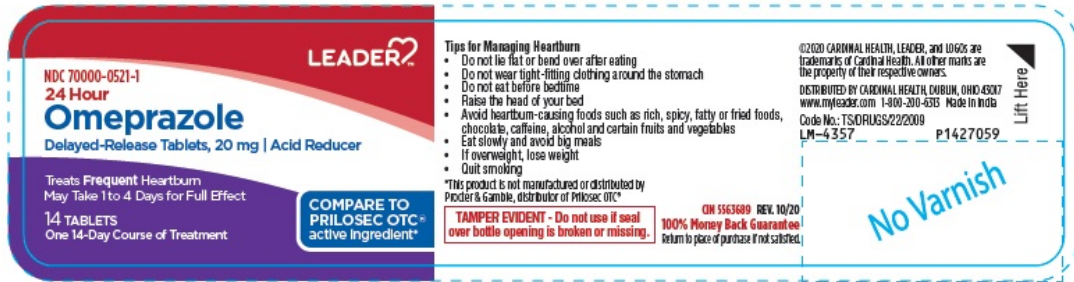
COMPARE TO

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)

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■ 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

Back of Top Ply (Page #2)

contact a Poison Control Center (1-800-222-1222) right away.

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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

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



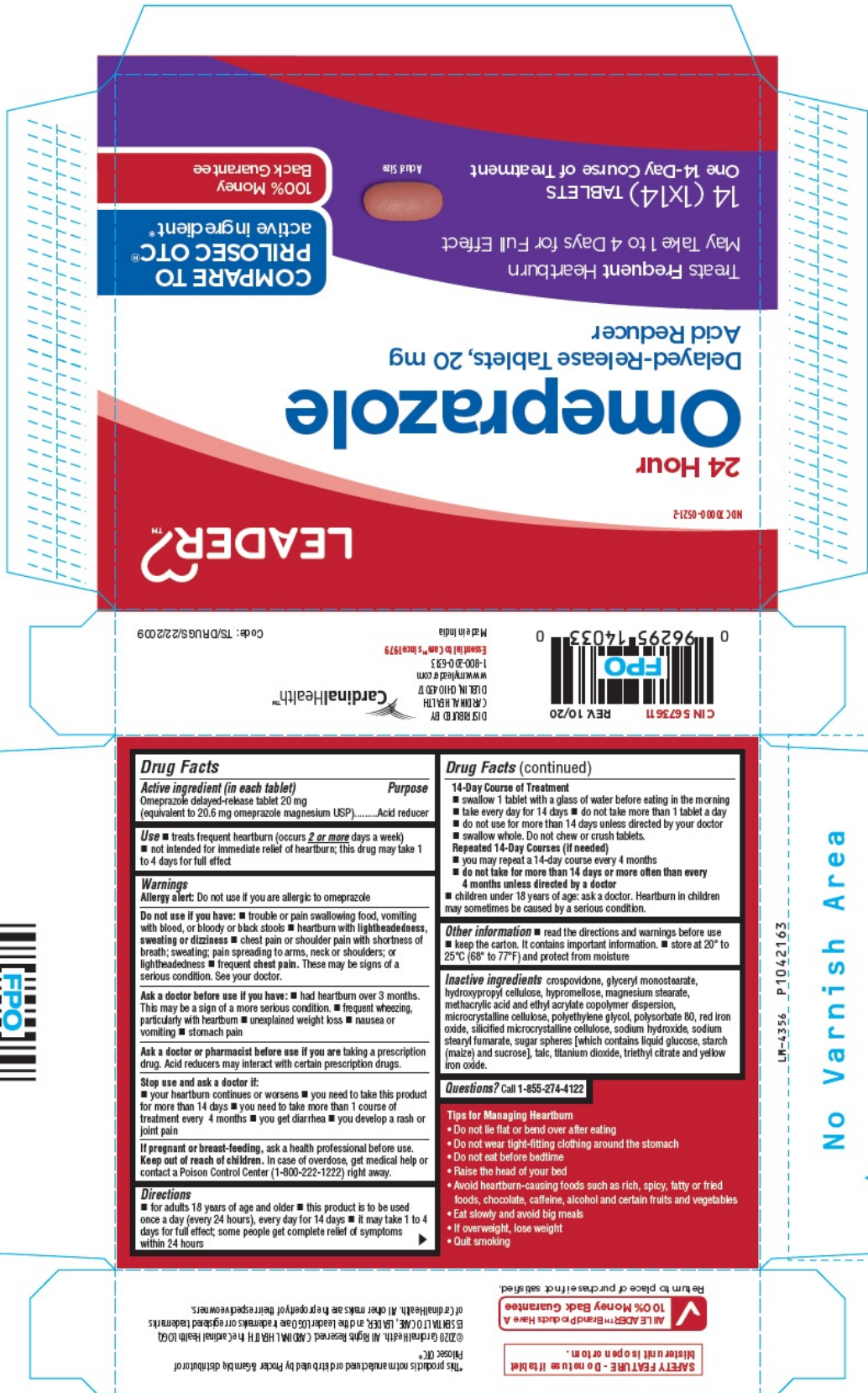
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg Blister Carton Label

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®
active ingredients*
100% Money
Back Guarantee
Actual Size

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



Drug Facts

Active ingredient (in each tablet)
Omeprazole delayed-release tablet 20 mg (equivalent to 20.6 mg omeprazole magnesium USP).....Acid reducer

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Drug Facts (continued)

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Inactive ingredients 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.

Questions? Call 1-855-274-4122

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- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

No Varnish Area

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



CardinalHealth™
DIXIE BLVD
DUBLIN, OH 43017
www.cardinal.com
1-800-20-0523
E-mail to: care@cs10179
Made in India
Cod: TS/DRUGS/222009

SAFETY FEATURE - Do not use if the blister
All LEADER™ Brand Products Have a
100% Money Back Guarantee

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ACID REDUCER
omeprazole tablet, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0521 |
| 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 |
|--|-----------------|
| 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: 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: OWZ8WG20P6) | |

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:70000- | 1 in 1 CARTON | 06/06/2018 | |

| | | | | |
|---|------------------|---|------------|--|
| 1 | 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 (063997360)

Registrant - Aurohealth LLC (078728447)

Establishment

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

Revised: 12/2023

Cardinal Health