

AMAZON BASIC CARE OMEPRAZOLE - omeprazole tablet, delayed release
Amazon.com Services LLC

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 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 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:

AMAZON.COM SERVICES LLC
410 TERRY AVENUE N.
SEATTLE, WA 98109

Made in India

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

**amazon
basic+care**

See current Drug Facts NDC 72288-409-05

**Omeprazole
Delayed-Release Tablets 20 mg**

Acid Reducer

**Treats Frequent
Heartburn!
24 HR**

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

Top Ply

basic care

See current Drug Facts NDC 72288-409-05

Omeprazole

Delayed-Release Tablets 20 mg

Acid Reducer

Treats Frequent Heartburn!

14 TABLETS

One 14-day course of treatment
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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

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

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P1434058 LM-5651

Lift Here

No Varnish

Top Ply (Page #1)

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

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

Purpose
Acid reducer

P1434058 LM-5651

HINGE

Back of Top Ply (Page #2)

Bottom Ply

HINGE

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

P1434058 LM-5651

Base (Page #3)

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

amazon

basic+care

Acid Reducer

**Compare to
Prilosec OTC®
active
ingredient***

NDC 72288-409-05

**See current Drug Facts
Omeprazole
Delayed-Release Tablets
20 mg**

Acid Reducer

**Treats Frequent Heartburn!
24 HR**

actual size

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



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

**amazon
basic+care**

Acid Reducer NDC 72288-409-01

**Compare to
Prilosec OTC®
active
ingredient***

**See current Drug Facts
Omeprazole
Delayed-Release Tablets 20 mg**

Acid Reducer

**Treats Frequent Heartburn!
24 HR
actual size**

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

14 (1 x 14) TABLETS

SAFETY FEATURE - Do not use if tablet blister unit is open or torn.

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* Lot:
 Expiry:

LM-5656

P1054809

Unvarnished Zone
 (dotted line not for printing)
 91 x 17 mm

- Tips for Managing Heartburn
- Do not lie flat or bend over after eating the stomach
 - 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

Questions? Call 1-855-274-4122

Inactive ingredients crospravone, glyceryl monostearate, hydroxypropylcellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer dispersion, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, sodium hydroxide, sodium starch glycolate, sugar spheres (which contains liquid glucose, starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide.

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.

14-Day Course of Treatment
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 ■ 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.

Drug Facts (continued)

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

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.

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.
Do not use if you have: ■ had heartburn over 3 months.
 This may be a sign of a more serious condition. ■ frequent heartburn, vomiting, or 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.
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 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:
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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.

Warnings
Allergy alert: ■ Do not use if you are allergic to omeprazole. Omeprazole may cause severe skin reactions.
 Symptoms may include:
 ■ rash ■ skin redness ■ blisters ■ hives
 If an allergic reaction occurs, stop use and seek medical help right away.

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

*This product is not manufactured or distributed by
 ASTRAZENCA PHARMACEUTICALS LP, owner of the
 registered trademark of Prilosec OTC®

Omeprazole
 Delayed-Release Tablets 20 mg



Acid Reducer

NDC 72288-409-01

Compare to
 Prilosec OTC®
 active
 ingredient*

See current Drug Facts

Omeprazole

Delayed-Release Tablets 20 mg
 Acid Reducer

Treats Frequent Heartburn!

24 HR



actual size

14 (1 x 14) TABLETSOne 14-day course of treatment
May take 1 to 4 days for full effect**AMAZON BASIC CARE OMEPRAZOLE**

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-409
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
CROSPVIDONE (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:72288-409-05	1 in 1 CARTON	05/15/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72288-409-01	1 in 1 CARTON	05/15/2024	
2		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:72288-409-61	2 in 1 CARTON	05/15/2024	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:72288-409-03	3 in 1 CARTON	05/15/2024	
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	05/15/2024	

Labeler - Amazon.com Services LLC (128990418)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(72288-409) , MANUFACTURE(72288-409)

Revised: 5/2024

Amazon.com Services LLC