

OMEPRAZOLE- omeprazole tablet, delayed release
PLD Acquisitions LLC DBA Avéma Pharma Solutions

OMEPRAZOLE MAGNESIUM DELAYED-RELEASE TABLETS

ACTIVE INGREDIENT

(in each tablet)

Omeprazole delayed-release tablet 20 mg
(equivalent to 20.6 mg omeprazole magnesium)

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 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 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 everyday 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

acetyl tributyl citrate, colloidal silicon dioxide, corn starch, croscarmellose sodium, hydroxypropyl cellulose, hypromellose 2910, magnesium stearate, methacrylic acid copolymer type C, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 3350, polyethylene glycol 8000, polyvinyl alcohol, red iron oxide, sucrose, talc, titanium dioxide, triethyl citrate

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

Principal display panel

†Compare to the active ingredient in Prilosec OTC®

24-hour

Omeprazole

Delayed-release tablets 20 mg

Acid reducer

Treat FREQUENT heartburn!

May take 1 to 4 days for full effect

Tablets

One-14-day course of treatment

†This product is not affiliated with, manufactured by or produced by the makers or owners of Prilosec OTC®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Manufactured by:

Avema Pharma Solutions

10400 NM 29th Terrace
Miami, FL 33172

Package label

Drug Facts (continued)

Store at 20° to 25° C (68° to 77° F)

Inactive ingredients acryl tributyl citrate, colloidal silicon dioxide, corn starch, croscarmellose sodium, hydroxypropyl cellulose, hypromellose 2910, magnesium stearate, methacrylic acid copolymer type C, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 3350, polyethylene glycol 600, polyvinyl alcohol, red iron oxide, sucrose, talc, titanium dioxide, triethyl citrate

Questions or comments?
Call 1-877-753-8835 Monday-Friday 9AM-5PM EST

This product is not affiliated with, manufactured by or produced by the makers or owners of Pilsosac OTC®.

DANGER: EVIDENCE DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

NDC 63548-297-14
*Compare to the active ingredient in Pilsosac OTC®


See current Drug Facts

24-hour Omeprazole

**Delayed-release tablets, 20 mg
Acid reducer**

Treats FREQUENT heartburn!
May take 1 to 4 days for full effect

14 Tablets
One 14-day course of treatment



Actual Size

63548-297-14
*Compare to the active ingredient in Pilsosac OTC®

See current Drug Facts

24-hour
Omeprazole
**Delayed-release tablets, 20 mg
Acid reducer**

Treats FREQUENT heartburn!
May take 1 to 4 days for full effect
SWALLOW-DO NOT CHEW

14 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)

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

Always alert:

- Omeprazole may cause severe skin reactions. Symptoms may include:
 - skin redness
 - 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 shoulder, 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
- rashes or hives
- stomach pain

Drug Facts (continued)

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 care 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, although 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
- **swallow whole. Do not crush or chew tablets.**

Repeat 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.**

Other information


- read the directions and warnings before use
- keep the carton. It contains important information.

Manufactured by:
Aveva Pharma Solutions
10400 NM 29th Terrace
Miami, FL 33172

Rxn: 1223
P13-1494K
FO08825

Lot No.:
Exp. Date:

1 BOTTLE INSIDE



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Aveva Pharma Solutions Acid Reducer

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-2970
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20.6 mg

Inactive Ingredients

Ingredient Name	Strength
ACETYLTRIBUTYL CITRATE (UNII: OZBX0N59RZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	pink (peach)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	O
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-2970-4	1 in 1 BOX	10/31/2024	
1		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63548-2970-8	1 in 1 BOX	10/31/2024	
2		28 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:63548-2970-2	1 in 1 BOX	10/31/2024	
3		42 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206582	10/31/2024	

Labeler - PLD Acquisitions LLC DBA Avéma Pharma Solutions (804087794)