

OMEPRAZOLE- omeprazole magnesium capsule, delayed release
Meijer, Inc.

Meijer Distribution, Inc. Omeprazole Drug Facts

Active ingredient (in each capsule)

Omeprazole delayed-release capsule 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 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 right away (1-800-222-1222).

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 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- do not use for more than 14 days unless directed by your doctor
- **swallow whole. Do not chew or crush capsules.**

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 20-25°C (68-77°F) and protect from moisture
- FDA approved dissolution test specifications differ from USP

Inactive ingredients

FD&C yellow # 6, ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

meijer®

Omeprazole

Delayed Release Capsules, 20 mg | Acid Reducer

COMPARE TO PRILOSEC OTC® ACTIVE INGREDIENT

24 HR

Treats FREQUENT Heartburn!

Mini Capsules

42 CAPSULES

THREE 14-DAY COURSES OF TREATMENT MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

See Current Drug Facts

Actual Size

meijer.

Omeprazole

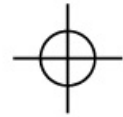
Delayed Release Capsules, 20 mg | Acid Reducer

24 HR

Treats FREQUENT Heartburn!

Mini Capsules

3 Bottles Inside



meijer.

Omeprazole

Delayed Release Capsules, 20 mg | Acid Reducer

24 HR

Treats FREQUENT Heartburn!

NDC 79481-0281-1

COMPARE TO
PRILOSEC OTC®
ACTIVE INGREDIENT*

Mini Capsules

42
CAPSULES

THREE 14-DAY COURSES OF TREATMENT
MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT



Actual Size

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

SAFETY FEATURE – DO NOT USE IF PRINTED FOIL SEAL UNDER CAP OR BAND AROUND THE CENTER OF EACH CAPSULE IS BROKEN OR MISSING.



3 Bottles inside

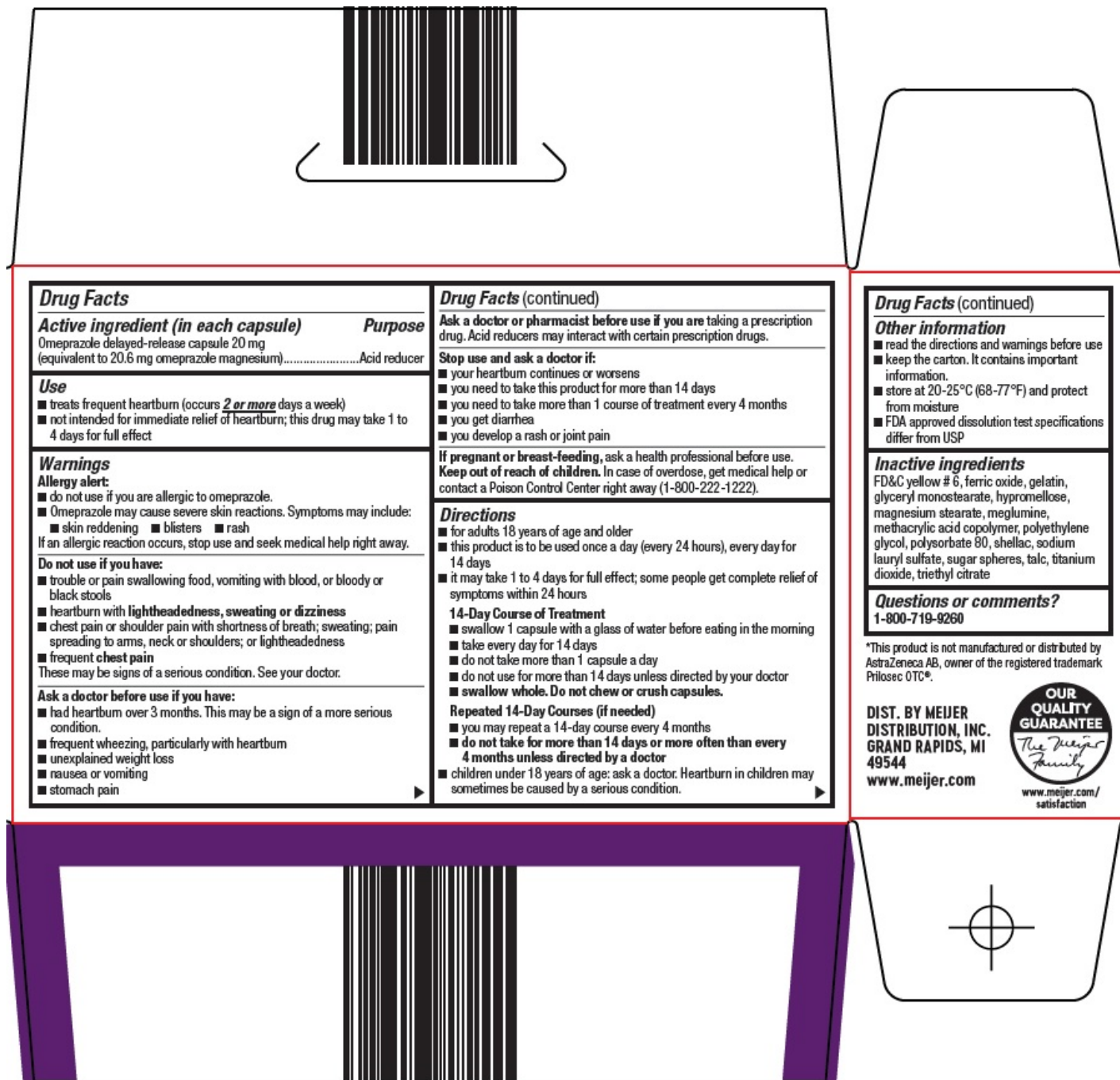
See Current Drug Facts

PID 4814016



7 08820 06621 2

24SD7 6E C1



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- unexplained weight loss
- nausea or vomiting
- stomach pain

Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredients

FD&C yellow # 6, ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium stearate, meglumine, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, shellac, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-800-719-9260

*This product is not manufactured or distributed by AstraZeneca AB, owner of the registered trademark Prilosec OTC®.

DIST. BY MEIJER DISTRIBUTION, INC.
GRAND RAPIDS, MI 49544
www.meijer.com



OMEPRAZOLE

omeprazole magnesium capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79481-0281 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

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

UNII:KG60484QX9)

OMEFRAZOLE

20 mg

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MEGLUMINE (UNII: 6HG8UB2MUJ) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| SHELLAC (UNII: 46N107B71O) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|----------|
| Color | WHITE, ORANGE | Score | no score |
| Shape | CAPSULE | Size | 14mm |
| Flavor | | Imprint Code | 24S |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:79481-0281-0 | 14 in 1 BOTTLE; Type 0: Not a Combination Product | 08/24/2023 | |
| 2 | NDC:79481-0281-1 | 3 in 1 CARTON | 08/24/2023 | |
| 2 | | 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 | ANDA216096 | 08/24/2023 | |

Labeler - Meijer, Inc. (006959555)