

OMEPRAZOLE- omeprazole tablet, delayed release
Meijer Distribution Inc

Meijer Distribution, Inc. Omeprazole Delayed Release Tablets 20 mg Drug Facts

Active ingredient (in each tablet)

Omeprazole 20 mg

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 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 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 20-25°C (68-77°F) and protect from moisture

Inactive ingredients

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Prilosec OTC[®]

24 HR

omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

SEE CURRENT DRUG FACTS

Treats Frequent Heartburn!

42 Tablets

three 14-day courses of treatment

may take 1 to 4 days for full effect

actual size



Safety Feature - Do not use if printed tablet blister unit is open or torn.

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

Compare to Prilosec OTC**

24 HR

omeprazole

Delayed Release Tablets 20 mg
Acid Reducer

SEE CURRENT DRUG FACTS

Treats Frequent Heartburn!

42 Tablets



Three 14-day courses of treatment may take 1 to 4 days for full effect

actual size

Drug Facts	
Active ingredient (in each tablet) Omeprazole 20 mg	Purpose Acid reducer
Use Take 1 tablet with each meal (occasionally with the evening meal) if prescribed 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: ulcers in the stomach or in the intestines, or if you are taking aspirin, ibuprofen, or other painkillers; or if you are taking other drugs that can irritate the stomach.	
Asks doctor or pharmacist if you have: ulcers in the stomach or in the intestines, or if you are taking aspirin, ibuprofen, or other painkillers; or if you are taking other drugs that can irritate the stomach.	
Stop use and ask doctor if: you need to take more than 1 course of treatment over 14 months, you get diarrhea, or you develop a rash or joint pain.	

Drug Facts (continued)	
If pregnant or breastfeeding, ask 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 (1-800-232-2222).	
Directions For adults 18 years of age and older: with immediate relief of heartburn, take 1 to 2 tablets with meals for 14 days. 14-Day Course of treatment: Take 1 tablet with each meal and at bedtime for 14 days. Repeat 14-Day Course as if needed: You may repeat the 14-day course every 4 months, but do not take for more than 14 days or more often than every 4 months unless directed by a doctor. Child or teen use: Ask doctor or pharmacist if you are 18 years old or younger.	
Other information Read the directions and warnings before use. Store at 20° to 25°C (68° to 77°F) and protect from moisture.	
Inactive ingredients carnaubawax, croscarmellose, hydroxypropyl methylcellulose, hypromellose, lactose, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, titanium dioxide, and hydroxypropyl methylcellulose.	
Questions or comments? 1-800-776-2260	

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Delayed Release Tablets 20 mg
Acid Reducer

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

Made in Israel
DST. BY MEIJER DIS TRIBUTION, INC.
GRAND RAPIDS, MI 495 44
www.meijer.com



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OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-915
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	BROWN	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-915-74	14 in 1 CARTON	02/29/2008	06/01/2014
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41250-915-30	2 in 1 CARTON	02/29/2008	05/01/2014
2		14 in 1 CARTON		
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41250-915-55	3 in 1 CARTON	02/29/2008	
3		14 in 1 CARTON		

3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:41250-915-01	1 in 1 CARTON	03/23/2011	
4		14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:41250-915-02	2 in 1 CARTON	09/02/2011	
5		14 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:41250-915-03	3 in 1 CARTON	09/02/2011	
6		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
NDA	NDA022032	02/29/2008	

Labeler - Meijer Distribution Inc (006959555)

Revised: 5/2019

Meijer Distribution Inc