

**ACID REDUCER - omeprazole tablet, delayed release**  
**Wal-Mart Stores, Inc.**

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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

***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:**

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

**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 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: Walmart Inc.,  
Bentonville, AR 72716  
PRODUCT OF INDIA  
TS/DRUGS/22/2009**

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

***equate*<sup>TM</sup>**

**NDC 49035-983-05**

**Omeprazole**

**Delayed-Release**

**Tablets 20 mg**

**24 HR**

**ACID REDUCER**

Treats **Frequent** Heartburn!

**14 TABLETS**

One 14-day course of treatment

•May take 1 to 4 days for full effect

# Top Ply



**equate™**  
**Omeprazole**  
Delayed-Release Tablets 20 mg

Acid Reducer  
Treats Frequent Heartburn!  
24 HR

14 TABLETS

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May take 1 to 4 days for full effect

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

**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
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- Raise the head of your bed
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- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

how2recycle.info

PLASTIC BOTTLE

Satisfaction guaranteed -  
For questions or comments  
please call 1-888-287-1915.

DISTRIBUTED BY: Walmart Inc.,  
Bentonville, AR 72716  
PRODUCT OF INDIA

TS/DRUGS/22/2009 535063 LM-3473

Lift here

## Active ingredient (in each tablet)

Omeprazole delayed-release tablet 20 mg (equivalent to 20.6 mg omeprazole magnesium USP) ..... 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:** ■ warfarin, clopidogrel or cilostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine) **Stop use and ask a doctor if:** ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days

# Back of Top Ply

# Bottom Ply

■ 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 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 1-888-287-1915**

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

3 PACK  
equate™

NDC 49035-983-62

Compare to Prilosec OTC®  
active ingredient\*

Omeprazole  
Delayed-Release  
Tablets 20 mg

**24 HR**

**ACID REDUCER**

Treats **Frequent** Heartburn!

•May take 1 to 4 days for full effect

**Actual Size**

**42**

**TABLETS**

*Three 14-day courses of treatment*

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  - Raise the head of your bed
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  - 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.**

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716  
 PRODUCT OF INDIA  
 \*This product is not manufactured or distributed by ASTRAZENCA PHARMACEUTICALS LP, owner of the registered trademark of Prilosec OTC®  
 IS/DRUGS/22/2009



LM-3472

Lot: \_\_\_\_\_  
 Expiry: \_\_\_\_\_

**3 PACK**  
 THREE 14-DAY COURSES OF TREATMENT

**equate™**

**Omeprazole**  
 Delayed-Release Tablets 20 mg

NDC 49035-983-62

Compare to Prilosec OTC® active ingredient\*

**Omeprazole**  
 Delayed-Release Tablets



## ACID REDUCER

omeprazole tablet, delayed release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-983
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 (12 MPA.S AT 5%) (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: 4R4HF16D95)	
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 MP.A.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:49035-983-62	3 in 1 CARTON	06/06/2018	
1	NDC:49035-983-05	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	ANDA206877	06/06/2018	

**Labeler** - Wal-Mart Stores, Inc. (051957769)

**Registrant** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(49035-983) , MANUFACTURE(49035-983)