

## **ACID REDUCER - omeprazole tablet, delayed release**

### **Bi-Mart**

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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)

##### **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 **1-800-935-6737**

\*This product is not manufactured or distributed by the owner of the registered trademark Prilosec OTC®

Distributed by:

**BI-MART**  
**Eugene, OR 97402**  
Made in India

Code: TS/DRUGS/22/2009

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

**BI-MART        NDC 37835-189-14**  
**ACID REDUCER**  
**Omeprazole**  
**Delayed-Release Tablets 20 mg**  
**TREATS FREQUENT HEARTBURN**  
**OCCURRING 2 OR MORE DAYS A WEEK**  
**14 TABLETS**  
**ONE 14-DAYCOURSE OF TREATMENT**

# Top Ply

**BI-MART** NDC 37 835-189-14

**ACID REDUCER**  
**OMEPRAZOLE**  
DELAYED-RELEASE TABLETS 20 mg

**14 TABLETS** TREATS FREQUENT HEARTBURN OCCURRING 2 OR MORE DAYS A WEEK ONE 14-DAY COURSE OF TREATMENT

**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.**

Made in India  
Code No.: TS/DRUGS/22/2009 LM-3144

Lift Here

Distributed by:  
BI-MART  
Eugene, OR 97402  
68911-014-11-0

No Varnish

## Top Ply (Page #1)

**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 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 ▶

## Back of Top Ply (Page #2)

## Bottom Ply

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 1-800-935-6737

## Base (Page #3)

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

**BI-MART** NDC 37835-189-14  
**ACID REDUCER**  
**Omeprazole Delayed-Release**  
**Tablets 20 mg**  
**TREATS FREQUENT HEARTBURN**

**OCCURRING 2 OR MORE DAYS A WEEK  
14 TABLETS  
ONE 14-DAY COURSE OF TREATMENT**



**ACID REDUCER**

omeprazole tablet, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37835-189
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OMEPRAZOLE MAGNESIUM</b> (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE (35 .MU.M)</b> (UNII: 40UAA97IT9)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)	
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HFI6D95)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>DEXTROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYDROXYPROPYL CELLULOSE (45000 WAMW)</b> (UNII: 8VAB711C5E)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: OWZ8WG20P6)	

## Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE (Oblong)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	Z;69
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37835-189-14	1 in 1 CARTON	06/06/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:37835-189-42	3 in 1 CARTON	06/06/2018	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA206877	06/06/2018	

**Labeler** - Bi-Mart (027630078)

**Registrant** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(37835-189) , MANUFACTURE(37835-189)

Revised: 11/2022

Bi-Mart