ACID REDUCER - omeprazole tablet, delayed release
Aurohealth LLC

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 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 (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:
AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648

Made in India

Code: TS/DRUGS/22/2009

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

AUROHEALTH
NDC 58602-729-05
See current Drug Facts
Omeprazole Delayed-Release Tablets 20 mg
ACID REDUCER
*Treats **Frequent** Heartburn!*
24 HR
14 TABLETS
One 14-day course of treatment
May take 1 to 4 days for full effect

Top Ply

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NDC 58602-729-05

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- 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

P1423434

Lift Here

No Varnish

Top Ply
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Active ingredient (in each tablet) ***Purpose***

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 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

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Bottom Ply

contact a Poison Control Center (1-800-222-1222) right away.

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

AUROHEALTH
NDC 58602-729-05
See current Drug Facts
Compare to Prilsec OTC®
Active Ingredient*
Omeprazole Delayed-Release
Tablets 20 mg
ACID REDUCER
*Treats **Frequent** Heartburn!*
24 HR
14 TABLETS
One 14-day course of treatment
May take 1 to 4 days for full effect

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

AUROHEALTH
NDC 58602-729-65

See current Drug Facts
Compare to Prilosec OTC®
Active Ingredient*
Omeprazole Delayed-Release
Tablets 20 mg
ACID REDUCER
*Treats **Frequent** Heartburn!*
24 HR
14 (2x7) TABLETS
One 14-day course of treatment
May take 1 to 4 days for full effect

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg Container Carton Label 14(1x14) Tablets

AUROHEALTH
NDC 58602-729-01
See current Drug Facts
Compare to Prilosec OTC®
Active Ingredient*
Omeprazole Delayed-Release
Tablets 20 mg
ACID REDUCER
*Treats **Frequent** Heartburn!*
24 HR
14 (1x14) TABLETS
One 14-day course of treatment
May take 1 to 4 days for full effect

ACID REDUCER

omeprazole tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-729
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
CROSPOVIDONE (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: 4R4HFI6D95)	
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 MPA.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:58602-729-05	1 in 1 CARTON	06/06/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-729-61	2 in 1 CARTON	06/06/2018	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-729-62	3 in 1 CARTON	06/06/2018	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-729-65	2 in 1 CARTON	06/06/2018	
4	NDC:58602-729-64	7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:58602-729-01	1 in 1 CARTON	06/06/2018	
5		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:58602-729-02	2 in 1 CARTON	06/06/2018	
6		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:58602-729-03	3 in 1 CARTON	06/06/2018	

7		14 in 1 BLISTER PACK; 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 - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-729) , MANUFACTURE(58602-729)

Revised: 9/2019 Aurohealth LLC