ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release
Aurohealth LLC

Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg*

Drug Facts

Active ingredient (in each capsule)

*Esomeprazole 20 mg
(Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium dihydrate USP)

Purpose

Acid reducer

Uses

- 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 esomeprazole.
■ Esomeprazole 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
- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- may take 1 to 4 days for full effect

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
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

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 before use. 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)
- Meets USP dissolution test 2

Inactive ingredients

colloidal silicon dioxide, FD&C blue no.1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion, mono and di glycerides, polysorbate 80, propylene glycol, shellac, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains liquid glucose, starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide.

Questions or comments?

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

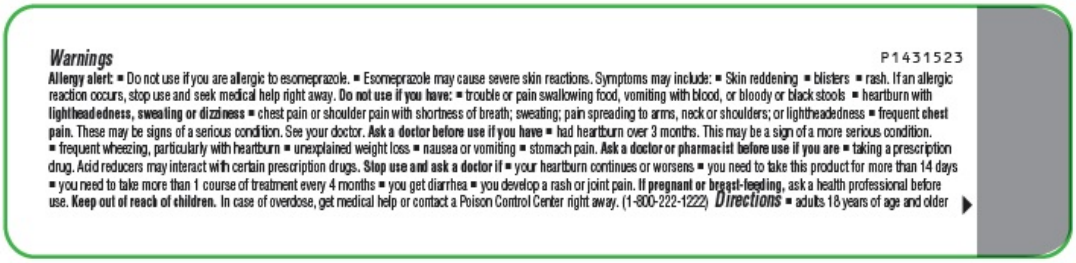
Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsule Container Label)

AUROHEALTH
NDC 58602-809-05
Esomeprazole Magnesium
Delayed-Release
Capsules USP 20 mg*
Acid Reducer
24 HR
May take 1 to 4 days
for full effect
Treats Frequent Heartburn
14 Capsules
One 14-day course of treatment

Top Ply

Top Ply
(Page #1)



Back of Top Ply
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Bottom Ply

Base
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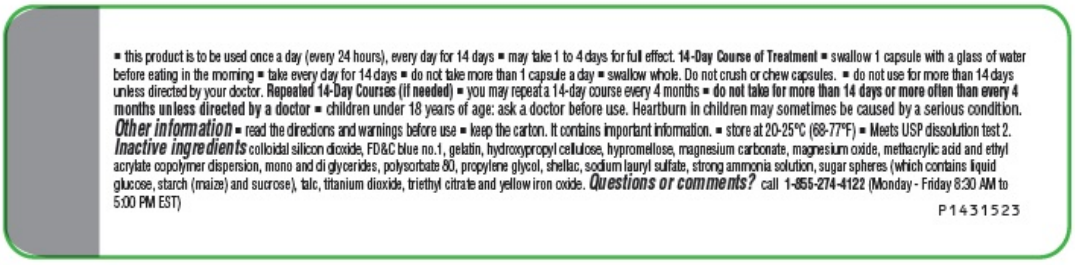

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsule Container Carton)

#Compare to Nexium® 24 HR
Active ingredient
AUROHEALTH
NDC 58602-809-05
See new warning information

Esomeprazole Magnesium
Delayed-Release
Capsules USP
20 mg*
Acid Reducer
24 HR
Treats Frequent Heartburn

May take 1 to 4 days for full effect
14 Capsules
One 14-day Course of treatment

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (28 Capsule Container Carton)

AUROHEALTH
NDC 58602-809-61
#Compare to Nexium® 24 HR Active ingredient

See new warning information
Esomeprazole Magnesium
Delayed-Release Capsules USP
20 mg*
Acid Reducer
24 HR
Treats Frequent Heartburn
May take 1 to 4 days for full effect
28 Capsules
(2 bottles of 14 each)
Two 14-day courses of treatment

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsule Container Carton)

AUROHEALTH
NDC 58602-809-05
#Compare to Nexium® 24 HR Active ingredient
See new warning information
Esomeprazole Magnesium
Delayed-Release
Capsules USP
20 mg*
Acid Reducer
24 HR
Treats Frequent Heartburn

May take 1 to 4 days for full effect

14 Capsules
One 14-day Course of treatment

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-809
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ESOMEPRAZOLE MAGNESIUM DIHYDRATE (UNII: 36H71644EQ) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
AMMONIA (UNII: 5138Q19F1X)	
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)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	I81
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-809-05	1 in 1 CARTON	10/16/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-809-61	2 in 1 CARTON	10/16/2017	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-809-62	3 in 1 CARTON	10/16/2017	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA209339	10/16/2017	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-809) , MANUFACTURE(58602-809)

Revised: 12/2022 Aurohealth LLC