

**ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release
WALGREEN CO.**

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

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)

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200 WILMOT RD., DEERFIELD, IL 60015
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MADE IN INDIA

Code: TS/DRUGS/22/2009

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

MAY TAKE 1 TO 4 DAYS
FOR FULL EFFECT

Walgreens

NDC 0363-0508-05

ACID REDUCER

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP 20 mg*

CAPSULES 24 HOUR

*Treats frequent heartburn

14 CAPSULES

ONE 14-DAY COURSE OF TREATMENT

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

Walgreens

ACID REDUCER
Esomeprazole Magnesium 24 HOUR Capsules

DELAYED-RELEASE CAPSULES USP 20 mg*
 • Treats frequent heartburn
14 CAPSULES
 ONE 14-DAY COURSE OF TREATMENT

NDC 0363-0508-05

DO NOT USE IF SEAL IMPRINTED WITH "SEALED FOR YOUR PROTECTION" UNDER THE BOTTLE CAP IS BROKEN OR MISSING
 KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION

Walgreens Pharmacist Recommended. Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.
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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

LM-4646 P1428681

Lift Here

No Varnish

Warnings

Allergy alert: Do not use if you are allergic to esomeprazole. 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

LM-4646 P1428681

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)

LM-4646 P1428681

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

Walgreens

Compare to
 Nexium® 24HR
 active ingredient

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

NDC 0363-0508-05

ACID REDUCER
Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP 20 mg*
 CAPSULES 24 HOUR

*Treats frequent heartburn

14 CAPSULES
ONE 14-DAY COURSE OF TREATMENT

ACTUAL SIZE
SEE NEW WARNING INFORMATION



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

Walgreens
24HR

Compare to Nexium®
active ingredient

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

NDC

0363-0508-08

ACID REDUCER

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP 20 mg*
CAPSULES 24 HOUR

*Treats frequent heartburn

28 CAPSULES

TWO 14-DAY COURSE OF TREATMENT

ACTUAL SIZE
SEE NEW WARNING INFORMATION



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (42 Capsules Container Carton)

Walgreens

Compare to Nexium® 24HR active ingredient

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

NDC

0363-0508-10

ACID REDUCER

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP 20 mg*

CAPSULES 24 HOUR

*Treats frequent heartburn

42 CAPSULES

THREE 14-DAY COURSES OF TREATMENT

ACTUAL SIZE
SEE NEW WARNING INFORMATION



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0508
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: 3A3U0G171G)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (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	l81
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0508-05	1 in 1 CARTON	10/16/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0508-08	2 in 1 CARTON	10/16/2017	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-0508-10	3 in 1 CARTON	10/16/2017	
3		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	ANDA209339	10/16/2017	

Labeler - WALGREEN CO. (008965063)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(0363-0508) , MANUFACTURE(0363-0508)

