

# **ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release**

**Dr. Reddy's Laboratories Inc**

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**Drug Facts**

## **Active ingredient(s) in each capsule**

\* Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate, USP)

## **Purpose**

Acid reducer

## **Use(s)**

- 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 lightheadness
- 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 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 directions and warnings before use
- keep the carton. It contains important information.
- store at 20°C to 25°C (68°F to 77°F)
- this product meets USP Dissolution Test 3

## **Inactive ingredients**

FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide red, magnesium stearate, methacrylic acid copolymer, polysorbate 80, potassium hydroxide, propylene glycol, shellac, simethicone, sugar spheres, talc, titanium dioxide and triethyl citrate.

## **Questions or comments**

call toll-free weekdays 8 AM to 8 PM EST at **1-888-375-3784**

## **Tips for Managing Heartburn**

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

Distributor:

Dr. Reddy's Laboratories Inc.,

Princeton, NJ 08540

Made in India

Issued: 04/2024

## **Principal Display Panel**

Container Labeling

Top  
(PNL 1)

Dr.Reddy's NDC 43598-926-52

**Mini Capsules** Treats Frequent Heartburn  
May take 1 to 4 days  
for full effect

**Esomeprazole  
Magnesium**  
Delayed-Release Capsules, USP  
20 mg\*  
Acid Reducer (24)

**14 Capsules**  
One 14-day course of treatment

**TAMPER EVIDENT FEATURES: Do NOT**  
Use if seal under bottle cap imprinted  
with "SEALED FOR YOUR PROTECTION"  
or blue band around the center of  
each capsule is broken or missing.

**KEEP CAPTION FOR COMPLETE WARNINGS  
AND IMPORTANT INFORMATION.**

**Active Ingredient Purpose**  
(In each capsule)  
Esomeprazole 20 mg... Acid reducer  
(Each delayed-release capsule  
corresponds to 22.3 mg  
esomeprazole magnesium  
trihydrate, USP)

**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.

Distributed by:  
Dr. Reddy's Laboratories, Inc.  
Piscataway, NJ 08854-10

Made in India Issue: 04/2024

Lot#ECP 1500 x x x x x

PREL  
HERE

0.375

Top Inside  
(PNL 2)

**Do not use if you have:**

- trouble or pain  
swallowing food, vomiting  
with blood, or bloody or  
black stools ■ heartburn  
with light-headedness,  
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 ■ is using 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 rash or hives  
if pregnant or breastfeeding, ask  
a health professional before use.

**Keep out of reach of children.**  
In case of overdose, get medical

0.875

Bottom  
(PNL 3)

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

■ child or 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°C to  
25°C (68°F to 77°F) ■ this product meets  
USP Dissolution Test 3

**Inactive Ingredients**  
FD&C Blue #1, ferrous ferric oxide, gelatin,  
glyceryl monostearate, hydroxypropyl  
cellulose, hypromellose, iron oxide red,  
magnesium stearate, methacrylic acid  
copolymer, polyacrylate 80, potassium  
hydroxide, polyethylene glycol, stearic  
acid, sucrose, sugar spheres, t.b.t., titanium  
dioxide and triethyl citrate.

**Questions or comments? call**  
toll-free weekdays 8 AM to 8 PM EST at  
1-888-375-3784

Container Carton Labeling



### Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

TAMPER EVIDENT-FEATURES: Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or blue band around the center of each capsule is broken or missing. KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

### Drug Facts (continued)

**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
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- nausea or vomiting
- stomach pain

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### Drug Facts (continued)

**Repeated 14-Day Courses (if needed)**

- you may repeat a 14-day course every 4 months
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### Other information

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### Inactive ingredients

FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide red, magnesium stearate, methacrylic acid copolymer, poly sorbate 80, potassium hydroxide, propylene glycol, shellac, simethicone, sugar spheres, talc, titanium dioxide and triethyl citrate.

### Questions or comments?

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\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Nexium® 24HR. Nexium® is a registered trademark of AstraZeneca AB.

Clinically Proven to Treat Frequent Heartburn

Distributed by: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540

Made in India

Rev: 04/2024

Dr.Reddy's NDC 43598-926-52

Compare to the active ingredient in Nexium® 24HR Clear Minis™\*\*

Treats Frequent Heartburn  
May take 1 to 4 days for full effect

Mini Capsules

See new warning information

## Esomeprazole Magnesium

### Delayed-Release Capsules, USP

# 20 mg\*

Acid Reducer

24 HOUR



14 Capsules

One 14-day course of treatment

1 BOTTLE INSIDE

### Drug Facts

**Active ingredient (in each capsule)** Purpose  
Esomeprazole 20 mg.....Acid reducer  
(Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate, USP)

**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:**

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  - skin reddening
  - blisters
  - rash

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**Do not use if you have:**

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- 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.



LOT

EXP

# ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43598-926
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESOMEPRAZOLE MAGNESIUM (UNII: R6DXU4WAY9) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

## Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SUCROSE (UNII: C151H8M554)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	

## Product Characteristics

Color	BLUE (light blue cap and dark blue body)	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	926
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-926-52	1 in 1 CARTON	12/01/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-926-28	2 in 1 CARTON	12/01/2024	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:43598-926-33	3 in 1 CARTON	12/01/2024	
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	ANDA207198	12/01/2024	

**Labeler** - Dr. Reddy's Laboratories Inc (802315887)

## Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited - FTO 3		918608162	analysis(43598-926) , manufacture(43598-926)

## Establishment

Name	Address	ID/FEI	Business Operations
Reed Lane Inc		001819879	pack(43598-926)

Revised: 7/2024

Dr. Reddy's Laboratories Inc