

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release

Dr. Reddy's Laboratories Inc

Drug Facts

Active ingredient(s) in each capsule

*Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 20.7 mg esomeprazole magnesium, 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

- 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

- each capsule contains: magnesium, 15 mg
- 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)

Inactive ingredients

acetyl tributyl citrate, dibutyl sebacate, FD&C Blue #1, ferrous ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, poloxamer, polysorbate 80, povidone, potassium hydroxide, propylene glycol, shellac, sugar, talc, titanium dioxide

Questions or comments

call toll-free weekdays 9 AM to 8 PM EST at 1-888-375-3784

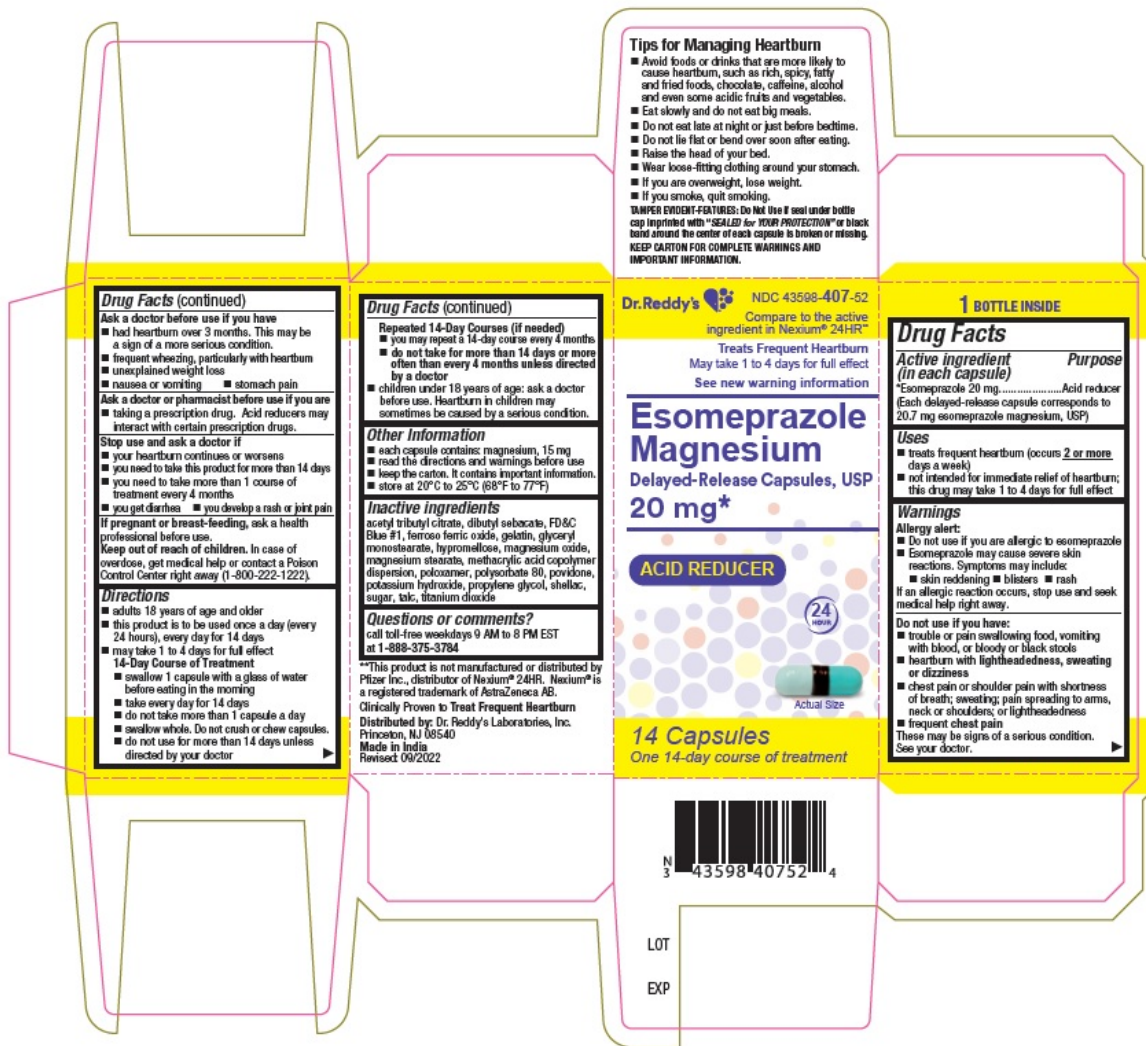
Tips for Managing Heartburn

- 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.

Revised: 09/2022

Carton label

Container Carton Label - 14s Count



Bottle label

Container Label - 14s Count

Top
(PNL 1)

Dr. Reddy's  NDC 43598-407-42
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

WARNING: EVILBENEFITURES: Do Not Use
If seal under the cap is imprinted with
• SEALER FOR YOUR PROTECTION* or black
band around the center of each capsule
is broken or missing.

**KEEP CAPSULES FROM COMPLETE WETNESS
AND IMPORTANT INFORMATION**

Active Ingredient Purpose
(in each capsule)
Esomeprazole 20 mg, Magnesium Acid reducer
(Each delayed-release capsule
corresponds to 20.7 mg
esomeprazole magnesium, 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 redness ■ 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

Distributed by:
Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540
Revised: 09/2022 Made in India
LOTEXP 1 5 0 0 X X X X X

PEEL HERE 

0.375

Top Inside
(PNL 2)

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 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)

0.875

Bottom
(PNL 3)

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 ■ each capsule
contains magnesium, 15 mg ■ read the
directions and warnings before use ■ keep the
carton in a cool, dry place ■ keep the
carton at 20°C to 25°C (68°F to 77°F)
■ store at 20°C to 25°C (68°F to 77°F)

Inactive Ingredients
acetyl tributyl citrate, dibutyl sebacate,
FD-30, Blue #1, ferrous lactate, croscel-
lulose, hydroxypropyl methylcellulose,
hydroxypropyl methylcellulose acetate,
magnesium stearate, methylparaben, poly-
ethylene glycol, polyethylene glycol,
polyethylene glycol, potassium
hydroxide, polyethylene glycol, stearic
acid, talc, titanium dioxide

Questions or comments? call
toll-free weekdays 9 AM to 8 PM EST at
1-888-375-3764

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

DC:43598-407

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
acetyltributyl citrate (UNII: OZBX0N59RZ)	
Dibutyl Sebacate (UNII: 4W5IH7FLNY)	
Ferrosferric Oxide (UNII: XM0M87F357)	
Gelatin (UNII: 2G86QN327L)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Hypromelloses (UNII: 3NXW29V3WO)	
Magnesium Oxide (UNII: 3A3U0GI71G)	
Magnesium Stearate (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
Poloxamer 188 (UNII: LQA7B6G8JG)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Povidone K30 (UNII: U725QWY32X)	
Talc (UNII: 7SEV7J4R1U)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
Potassium Hydroxide (UNII: WZH3C48M4T)	
Shellac (UNII: 46N107B71O)	
Sucrose (UNII: C151H8M554)	
Fd&C Blue No. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE (light blue cap) , BLUE (dark blue body)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	RDY;327
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-407-52	1 in 1 CARTON	05/16/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-407-27	2 in 1 CARTON	05/16/2018	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:43598-407-33	3 in 1 CARTON	05/16/2018	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:43598-407-74	2 in 1 CARTON	05/16/2018	
4	NDC:43598-407-70	7 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	ANDA207673	05/16/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited - FTO 3		918608162	analysis(43598-407) , manufacture(43598-407)

Revised: 9/2022

Dr. Reddy's Laboratories Inc