

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release

TIME CAP LABORATORIES, INC.

49483-718 Esomeprazole magnesium delayed release capsules USP, 20mg

Drug Facts

Active ingredient (in each capsule)

Esomeprazole 20 mg

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

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 include:

-skin reddening
-blisters
-rash

If an allergic reaction occurs, stop use and seek medical attention 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 (1-800-222-1222) right away.

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

1. swallow 1 capsule with a glass of water before eating in the morning
2. take every day for 14 days
3. do not take more than 1 capsule a day
4. swallow whole. Do not crush or chew capsules.
5. do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

1. you may repeat a 14-day course every 4 months
 2. **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)

Inactive ingredients black iron oxide, eudragit, FD&C blue 1, FD&C red 3, ferric oxide yellow, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, polysorbate 80, potassium hydroxide, shellac, simethicone, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate.

Questions or comments? Call **1-877-290-4008**

Coating/
Print Omit Area

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
<p>Active ingredient (in each capsule) Esomeprazole USP, 20 mg (Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)</p> <p>Purpose Acid reducer</p> <p>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</p> <p>Warnings Allergy alert: ■ Do not use if you are allergic to esomeprazole ■ Esomeprazole may cause severe skin reactions. Symptoms include: ■ skin redness, ■ hives, ■ rash If an allergic reaction occurs, stop use and seek medical attention right away.</p> <p>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</p>	<p>These may be signs of a serious condition. See your doctor.</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are ■ taking a prescription drug. Acid reducers may interact with certain prescription drugs.</p> <p>Stop use and see a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you get diarrhea ■ you develop a rash or joint pain</p> <p>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.</p> <p>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</p>	<p>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</p> <p>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</p> <p>■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F)</p> <p>Inactive ingredients black iron oxide, enduro, FD&C blue 1, FD&C red 3, ferric oxide yellow, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hydroxypropyl, magnesium stearate, polyborate 80, potassium hydroxide, shellac, croscellose, sodium lauryl sulfate, sugar spheres, titanium dioxide, triethyl citrate.</p> <p>Questions or comments? Call 1-877-290-4008</p>

Coating/
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timely

Esomeprazole Magnesium

Delayed-Release Capsules USP, 20 mg

Acid Reducer

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

NDC 49483-718-41

Actual Size 3 bottles inside

Actual Size 3 bottles inside

WINDOW

WINDOW

WINDOW

Esomeprazole Magnesium

Delayed-Release Capsules USP, 20 mg

Acid Reducer

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

See New Warning Information

24hr

ACTUAL SIZE

42 CAPSULES

Three 14-day courses of treatment

This product is not manufactured or distributed by Haleon group of companies, owner of the registered trademark Nexium® 24HR

Distributed by:
Time-Cap Labs, Inc.
7 Michael Avenue,
Farmingdale, NY 11735

Made in India
7187 1123

Lot No.:
Exp. Date:

3 948317184116

NDC 49483-718-45

timely

Esomeprazole Magnesium

Delayed-Release Capsules USP, 20 mg

Acid Reducer

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

24hr

14 CAPSULES

One 14-day course of treatment

TAMPER EVIDENT: DO NOT USE IF THE IMPRINTED FOIL SEAL UNDER BOTTLE CAP OR BAND AROUND THE CENTER OF EACH CAPSULE IS BROKEN OR MISSING

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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Distributed by: Time-Cap Labs, Inc., 7 Michael Avenue, Farmingdale, NY 11735
Made in India 7187 1123
Lot No.:
Exp. Date:

Varnish Omit Area

ESOMEPRAZOLE MAGNESIUM			
esomeprazole magnesium capsule, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-718
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		
SUCROSE (UNII: C151H8M554)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
FERROSFERRIC OXIDE (UNII: XM0M87F357)			

METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)
HYPROMELLOSES (UNII: 3NXW29V3WO)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
GELATIN (UNII: 2G86QN327L)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SHELLAC (UNII: 46N107B71O)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
MAGNESIUM STEARATE (UNII: 70097M6I3O)

Product Characteristics

Color	purple (PURPLE (golden cap and violet transparent body having light violet to violet colour band))	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-718-41	3 in 1 CARTON	11/14/2023	
1		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	ANDA217264	11/14/2023	

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-718)

