ESOMEPRAZOLE MAGNESIUM DELAYED RELEASE- esomeprazole magnesium capsule, delayed release WALGREENS

718T-Walgreens- Esomeprazole Magnesium 20mg DR

Drug Facts

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

- 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)

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? 1-877-290-4008





Varnish Omit

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

Walgreens

Compare to the active ingredient in Nexium® 24HR#

ACID REDUCER

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP, 20 mg

24 Hour Capsules

ACTUAL SIZE

• Treats frequent heartburn

14 CAPSULES

ONE 14-DAY COURSE OF TREATMENT

SEE NEW WARNING INFORMATION

RETAIN CARTON FOR COMPLETE RNINGS AND PRODUCT INFORMATION

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 Symptoms include:
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 medical attention right away.
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- dizziness
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Drug Facts (continued)

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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? 1-877-290-4008

Tips for Managing Heartburn Avoid foods or drinks t

- fined toods, chocolets, caffeins, aloohol and even some acciding and anothology and on one ability meals.

 Do not eat less at night or just before bedfine. Do not lie flat or bend over soon after setting. Flats the head of your bed. Wear loose-fring obthing remond your stomach. If you are overweight, lose weight. If you smoke, quit smoking.

NDC 0363-7810-45 W3ORG0525-F

Omit Varnish ITEM 700123 W00000-0000-0



LOT: EXP.:

Varnish Omit

Walgreens Pharmacist Recommended. Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands. ITEM 700123 NDC 0363-7810-45 W000000-0000-0 W3ORG0525-F DISTRIBUTED BY: WALGREEN CO., DEERFIELD
IIL 60015, 100% SATISFACTION GUARANTEED
walgreens.com ©2025 Walgreen Co. MADEIN INDIAI adults 18 years of age and older
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Inside



Outside

ESOMEPRAZOLE MAGNESIUM DELAYED RELEASE

esomeprazole magnesium capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-7810
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: 2300U9XXE4)			
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)			
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)			

FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
SUCROSE (UNII: C151H8M554)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SHELLAC (UNII: 46N107B710)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics			
Color	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:0363-7810- 45	1 in 1 CARTON	06/03/2025	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-7810- 82	2 in 1 CARTON	06/03/2025	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-7810- 41	3 in 1 CARTON	06/03/2025	
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	ANDA217264	06/03/2025	

Registrant - TIME CAP LABORATORIES INC (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(0363-7810)	

Revised: 4/2025 WALGREENS