ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release
LITTLE PHARMA, INC.

Curist Heartburn Relief (Esomeprazole)

Drug Facts

Active ingredient (in each capsule)

*Esomeprazole 20 mg (Each delayed-release capsule contains 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

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 doctor orpharmacist 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
- Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room temperature.]
- keep the carton. It contains important information.
- TAMPER-EVIDENT FEATURES: Do not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or blue band around center of each capsule is broken or missing.

Inactive Ingredients

FD&C blue no 1, FD&C red no 3, ferrosoferric oxide, gelatin, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer dispersion, mono and di glycerides, polysorbate 80, potassium hydroxide, propylene glycol, shellac, sugar spheres (corn starch and sucrose), talc, titanium dioxide and triethyl citrate.

Questions

Call toll-free weekdays 8:30 AM to 5 PM EST at **1-800-818-4555.**

Distributed by:

Little Pharma Inc.

New York, NY 10023

Curist

Heartburn Relief

Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg*

Acid Reducer

24 HR; Treats Frequent Heartburn

42 CAPSULES

Three 14-day courses of treatment

May take 1 to 4 days for full effect

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72559-011
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
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Product Characteristics

Color	pink	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	RG50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72559-011-07	14 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2021	
2	NDC:72559-011-06	3 in 1 CARTON	03/23/2021	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:72559-011-36	4 in 1 PACKAGE, COMBINATION	06/18/2024	
3		3 in 1 CARTON		
3		14 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212866	03/23/2021	

Labeler - LITTLE PHARMA, INC. (074328189)

Revised: 6/2024 LITTLE PHARMA, INC.