ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release
Camber Consumer Care Inc

Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg (OTC)

ACTIVE INGREDIENT (in each capsule)

Esomeprazole 20 mg
(*Each delayed-release capsule corresponds to 22.25 mg esomeprazole magnesium trihydrate USP).

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 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 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 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° to 25°C (68° to 77°F)

INACTIVE INGREDIENTS

Black iron oxide, FD&C Blue No. 1, FD&C Blue No. 2, gelatin, glyceryl monostearate, hydroxy propyl cellulose, hypromellose, magnesium stearate, methacrylic acid ethyl acrylate copolymer, potassium hydroxide, polysorbate 80, propylene glycol, shellac, simethicone, sodium lauryl sulfate, strong ammonia solution, sugar spheres (contains sucrose and corn starch), talc, titanium dioxide, triethyl citrate.

QUESTIONS OR COMMENTS?

call toll-free weekdays 9 AM to 5 PM EST at **1-888-588-1418.**

Distributed by:
Camber Consumer Care, Inc.

Piscataway, NJ 08854, USA.

PRINCIPAL DISPLAY PANEL

Esomeprazole Magnesium Delayed-Release Capsules, USP, 20 mg - Carton (Hetero)

Esomeprazole Magnesium Delayed-Release Capsules, USP, 20 mg - Carton (Annora)

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69230-320
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
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GELATIN (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: MB5IUD6JUA)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
AMMONIA (UNII: 5138Q19F1X)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	

Product Characteristics

Color	white (white opaque cap) , blue (blue opaque body)	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	H;E4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69230-320-31	1 in 1 CARTON	06/02/2020	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69230-320-32	2 in 1 CARTON	06/02/2020	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69230-320-33	3 in 1 CARTON	06/02/2020	
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	ANDA212507	06/02/2020	

Labeler - Camber Consumer Care Inc (079539968)

Establishment

Name	Address	ID/FEI	Business Operations
Hetero Labs Limited Unit III		676162024	manufacture(69230-320)

Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	manufacture(69230-320)

Revised: 4/2025

Camber Consumer Care Inc