ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release
Chain Drug Marketing Association Inc.

Quality Choice Esomeprazole Magnesium Delayed Release Capsules 666

ACTIVE INGREDIENT(in each capsule)

*Esomeprazole 20 mg

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

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 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 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 20-25ºC (68-77ºF)

INACTIVE INGREDIENT SECTION

FD&C blue 1, FD&C red 3, FD&C red 40, ferroso ferric oxide, gelatin, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer dispersion, mono and di-glycerides, polysorbate 80, potassium hydroxide, shellac, sodium lauryl sulfate, sugar spheres (contains corn starch, sucrose, water), talc, titanium dioxide, triethyl citrate.

QUESTIONS OR COMMENTS?

Call **1-800-883-3540** (Monday - Friday 8 am - 4 pm)

OTHER SAFETY INFORMATION

Tips of 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.

Do not use if seal under bottle cap imprinted with "SEALED FOR YOUR PROTECTION" or blue band around the center of each capsule is broken or missing.

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

PRINCIPAL DISPLAY PANEL

QC ® QUALITY CHOICE

NDC 83324-010-14

*Compare to the Active Ingredient in Nexium®

Esomeprazole Magnesium

Acid Reducer

Delayed-Release Capsules USP, 20 mg*

See new warning information

Treats Frequent Heartburn

24 HR Capsules

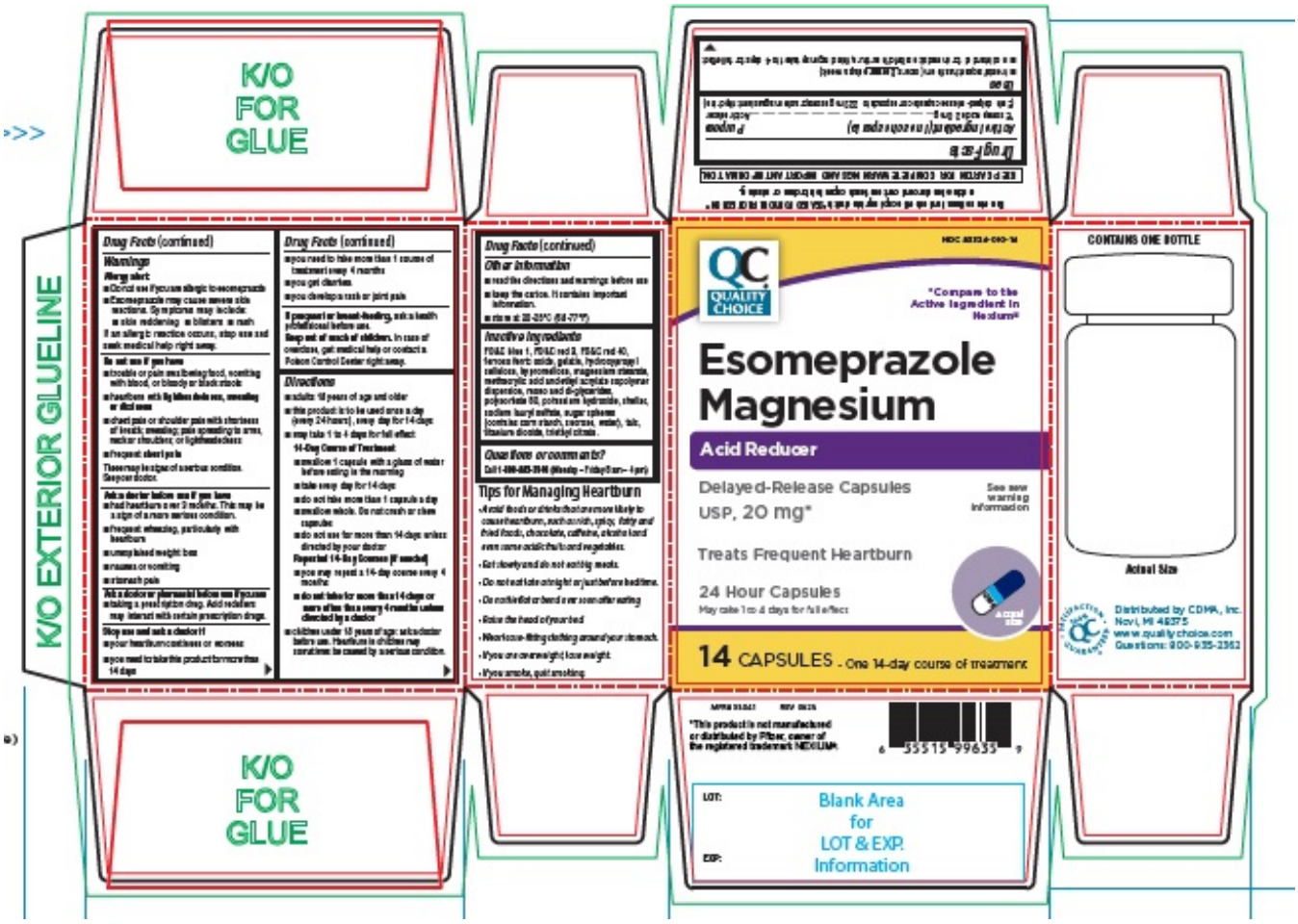
May take 1 to 4 days for full effect

14 CAPSULES - One 14-day course of treatment

FRONT COVER LABEL (PAPER)
AND TEXT PULLOUT

(PAPER) TEXT PULLOUT.
BACKS UP TO ABOVE COVER LABEL WITH DRUG FACT TEXT.

TOP LABEL (CLEAR LAMINATE)



QC ® QUALITY CHOICE

NDC 83324-010-42

*Compare to the Active Ingredient in Nexium®

Esomeprazole Magnesium

Acid Reducer

Delayed-Release Capsules USP, 20 mg*

See new warning information

Treats Frequent Heartburn

24 HR Capsules

May take 1 to 4 days for full effect

42 CAPSULES - One 14-day course of treatment

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83324-010
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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
GLYCERYL MONO AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	WHITE (opaque body) , BLUE (opaque cap)	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	G666
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-010-14	1 in 1 CARTON	03/13/2024	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:83324-010-42	3 in 1 CARTON	03/13/2024	
2		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	ANDA216149	03/13/2024	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(83324-010)

Revised: 3/2024 Chain Drug Marketing Association Inc.