ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release
CHAIN DRUG MARKETING ASSOCIATION INC

Drug Facts

Active ingredient (in each capsule)

*Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 20.7 mg esomeprazole magnesium, USP)

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 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 lightheadness
- 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 (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

- each capsule contains: magnesium, 15 mg
- read directions and warnings before use
- keep the carton. It contains important information
- store at 20 to 25°C (68 to 77°F)

Inactive ingredients

acetyl tributyl citrate, dibutyl sebacate, FD&C Blue #1, ferroso ferric oxide, gelatin, glyceryl monostearate, hypromellose, magnesium oxide, magnesium stearate,

methacrylic acid copolymer dispersion, poloxamer, polysorbate 80, povidone, potassium hydroxide, propylene glycol, shellac, sugar, talc, titanium dioxide

Questions or comments?

call toll-free weekdays 9 AM to 8 PM EST at **1-888-375-3784**

Tips for Managing Heartbun

- 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.

Bottle Label

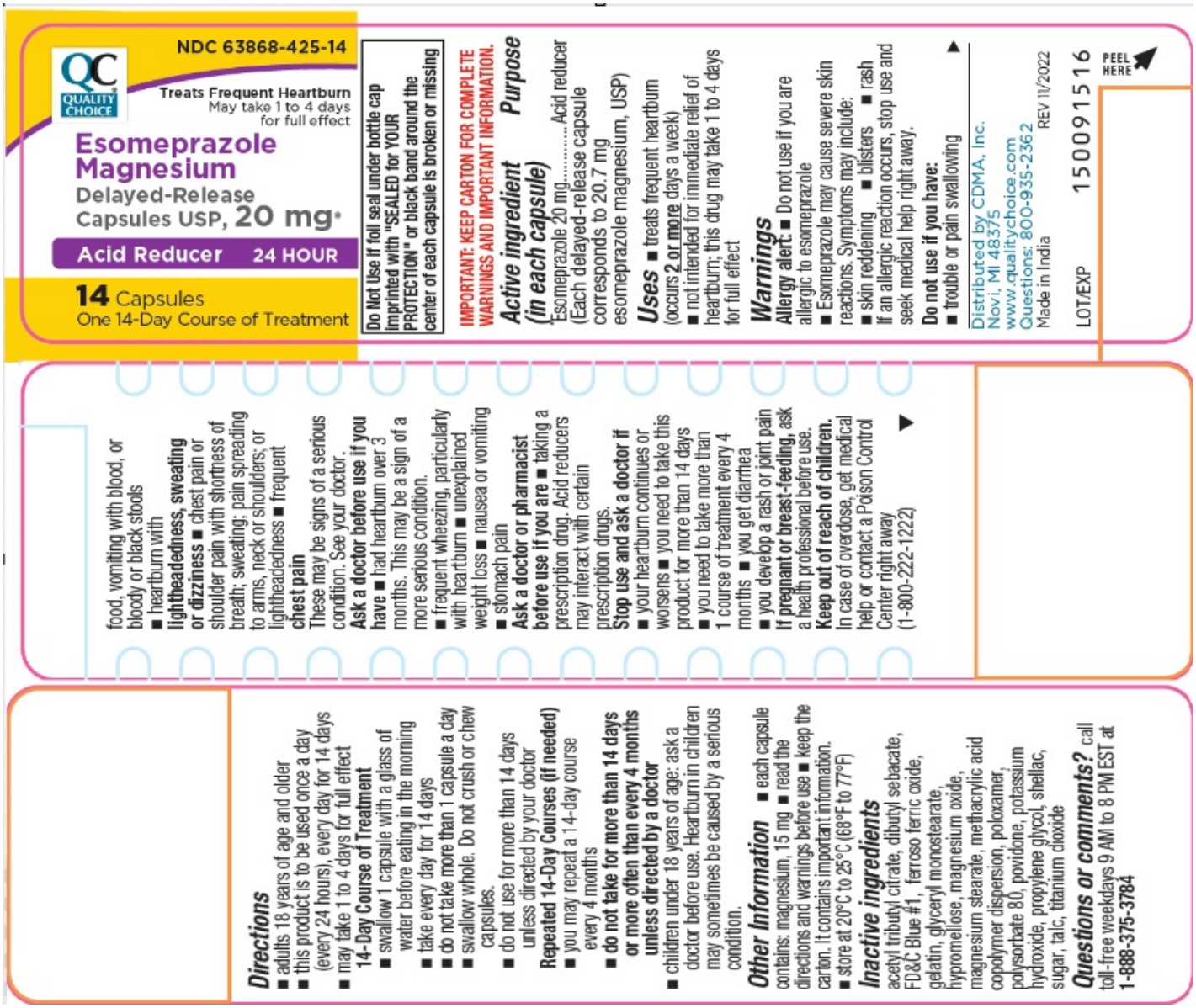
NDC 63868-425-14

QC QUALITY CHOICE

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

Esomeprazole
Magnesium
Delayed-Release
Capsules USP, 20 mg*
Acid Reducer 24 HOUR

14 Capsules
One 14-Day Course of Treatment



Carton Label

NDC 63868-425-42

QC QUALITY CHOICE

**Compare to the
Active Ingredient in
Nexium® 24HR

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

**Esomeprazole
Magnesium**

**Delayed-Release
Capsules USP, 20 mg*
Acid Reducer**

24 HOUR

42 Capsules
Three 14-Day Courses of Treatment

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-425(NDC:43598-407)
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
acetyltributyl citrate (UNII: 0ZBX0N59RZ)	
Dibutyl Sebacate (UNII: 4W5IH7FLNY)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Gelatin (UNII: 2G86QN327L)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Hypromelloses (UNII: 3NXW29V3WO)	
Magnesium Oxide (UNII: 3A3U0GI71G)	
Magnesium Stearate (UNII: 70097M6I30)	

Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A (UNII: NX76LV5T8J)	
Poloxamer 188 (UNII: LQA7B6G8JG)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Povidone K30 (UNII: U725QWY32X)	
Talc (UNII: 7SEV7J4R1U)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
Potassium Hydroxide (UNII: WZH3C48M4T)	
Shellac (UNII: 46N107B71O)	
Sucrose (UNII: C151H8M554)	
Fd&C Blue No. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE (light blue cap) , BLUE (dark blue body)	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	RDY;327
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-425-14	1 in 1 CARTON	07/06/2018	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63868-425-28	2 in 1 CARTON	03/15/2019	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:63868-425-42	3 in 1 CARTON	07/06/2018	
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	ANDA207673	07/06/2018	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Revised: 10/2024 CHAIN DRUG MARKETING ASSOCIATION INC