ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release
P & L Development, LLC

Esomeprazole Magnesium Delayed-Release Capsules 20 mg - Actavis

Drug Facts

Active ingredient (in each capsule)

Esomeprazole 20 mg
(*Each delayed-release capsule corresponds to 21.7 mg esomeprazole magnesium dihydrate)

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 a doctor or pharmacist before use if you are taking

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- diazepam (anxiety medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

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 us

- keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

gelatin, hypromellose, magnesium stearate, methacrylic acid copolymer dispersion type C, mono-and di-glycerides, polysorbate 80, sodium lauryl sulfate, sugar spheres (contain sucrose, corn starch and purified water), talc, titanium dioxide, triethyl citrate.

Each capsule is imprinted with blue pharmaceutical ink which contains butyl alcohol, dehydrated alcohol, FD&C Blue No 2 aluminum lake, isopropyl alcohol, propylene glycol, shellac, strong ammonia solution and having two parallel bands which contains FD&C Blue No 2 aluminum lake, gelatin and polysorbate 80

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

**Compare to the active ingredient in Nexium® 24R

24-hour

esomeprazole magnesium

delayed-release capsules

USP, 20 mg*

acid reducer

treats frequent heartburn

may take 1 to 4 days for full effect

**This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Nexium® 24HR.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP OR BAND AROUND THE CENTER OF EACH CAPSULE IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

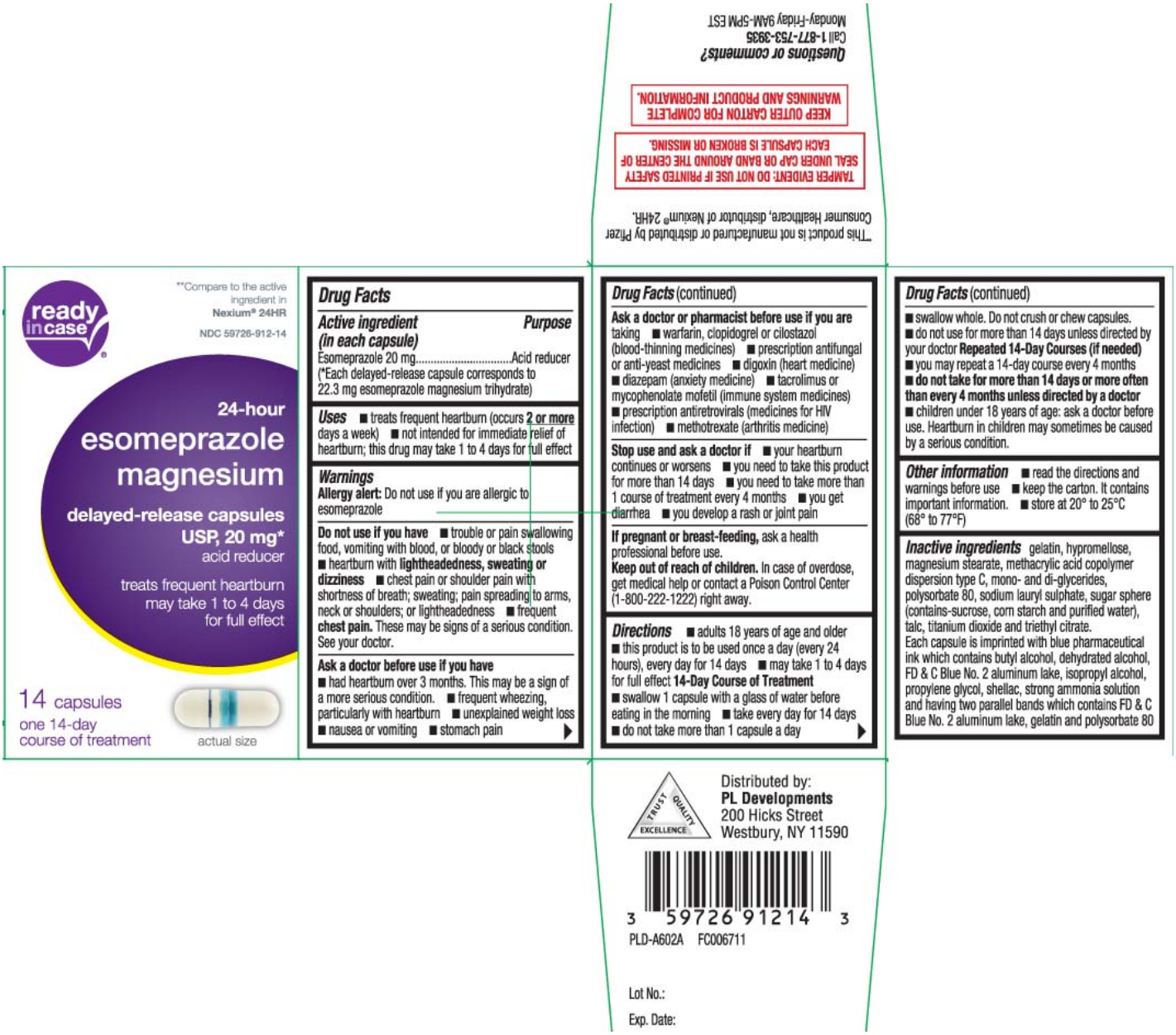
Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Package label



READYinCASE 24-Hour esomeprazole magnesium

ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59726-912(NDC:69238-1050)
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
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	AMNEAL1050
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-912-14	1 in 1 CARTON	01/31/2020	12/31/2025
1		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	ANDA209716	01/31/2020	12/31/2025

Labeler - P & L Development, LLC (800014821)

Revised: 4/2023 P & L Development, LLC