

RIOPAN- esomeprazole capsule, delayed release
OPMX LLC

RIOPAN Esomeprazole Magnesium 20mg w/ 14 Capsules

Drug Facts

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 I 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 a 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 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, hydroxyl 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?

Call toll - free weekdays 9 AM to 5 PM EST at 1-888-588-1418

Do Not Use if carton is opened or if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or band around the center of each capsule is broken or missing.

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

Phone:619-600-5632

NDC 69729-791-14

Riopan

ESOMEPRAZOLE+MAGNESIUM

Delayed-Release Capsules USO

Capsulas de liberacion retardada

HEARTBURN RELIEF

REDUCE ACIDEZ ESTOMACAL

- **ACID REFLUX** / REFLUJO
- **HEARTBURN** / AGRURAS
- **STOMACH BURNING** / ARDOR ESTOMACAL

14 CAPSULES 20 mg*

MAY TAKE 1 TO 4 DAYS FOR FULL EFFECT

PUEDE TARDAR 1 A 4 DIAS EN HACER EFECTO COMPLETO

- Tips for 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.

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Rev. 02/2006
Item # BRX1150



NO VARNISH AREA

Batch:
Exp:

**KEEP CARTON FOR COMPLETE WARNINGS
AND IMPORTANT INFORMATION.**

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Warnings
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■ 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.

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■ 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.

Drug Facts (continued)

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

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■ swallow 1 capsule with a glass of water before eating in the morning ■ take every day for 14 days
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Repeated 14-Day Courses (if needed)
■ you may repeat a 14-day course every 4 months
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Drug Facts (continued)

Other information
■ read the directions and warnings before use
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Made for
San Diego, CA 92154

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Phone: 619-600-5632

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Drug Facts
(continued
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Drug Facts (continued)

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.

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Drug Facts (continued)

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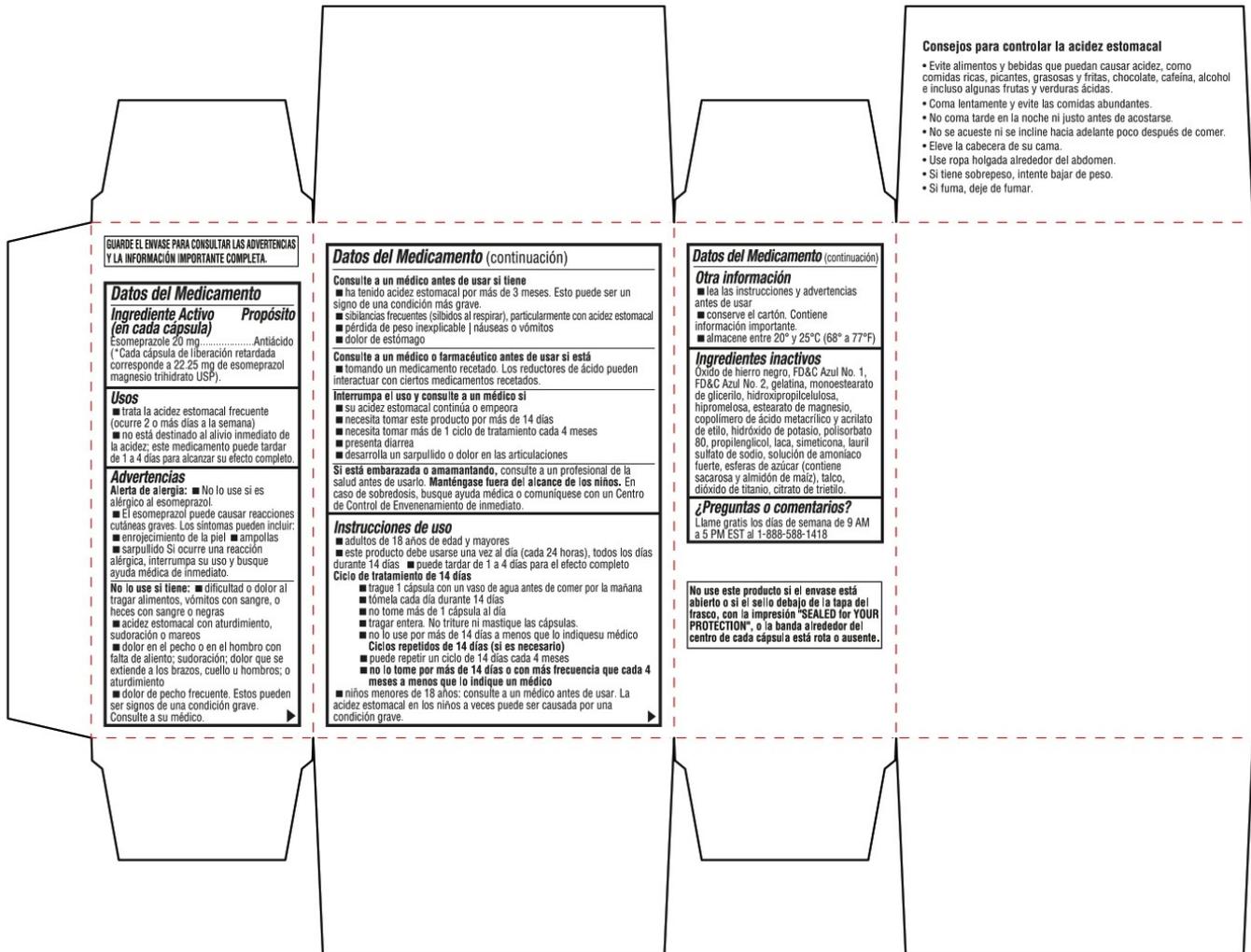
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RIOPAN

esomeprazole capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-791
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
METHACRYLIC ACID-ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGNESIUM STEARATE (UNII: 70097M6130)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
GELATIN (UNII: 2G86QN327L)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
SHELLAC (UNII: 46N107B71O)
TALC (UNII: 7SEV7J4R1U)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
AMMONIA (UNII: 5138Q19F1X)
SUCROSE (UNII: C151H8M554)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
STARCH, CORN (UNII: O8232NY3SJ)
DIMETHICONE (UNII: 92RU3N3Y1O)

Product Characteristics

Color	white (White opaque cap / Blue opaque body size)	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	HE4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-791-14	1 in 1 CARTON	03/04/2026	
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	ANDA212507	03/04/2026	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	manufacture(69729-791)

