

# ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release

Amneal Pharmaceuticals NY LLC

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**Esomeprazole Magnesium Delayed-Release Capsules, USP  
20 mg/Acid Reducer (OTC)**

## **Drug Facts**

<b>Active ingredient (in each capsule)</b>	<b>Purpose</b>
Esomeprazole 20 mg	Acid reducer
(*Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)	

## **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 the 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)
- Tamper Evident: Do not use if printed safety seal under cap or band around the center of each capsule is broken or missing.

## Inactive ingredients

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

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

## Questions or comments?

**Call toll-free 1-877-835-5472**

Mon – Fri 9AM – 5PM EST.

Made in India

For most recent product information, visit [www.amneal.com](http://www.amneal.com)

## Principal Display Panel




**NDC 69238-1050-4**

**Esomeprazole Magnesium Delayed-Release Capsules, USP/Acid Reducer (OTC)**

**20 mg**

**14 Capsules (Container Label)**

**Amneal Pharmaceuticals LLC**

<p>9MM BLANK FOR GLUE AREA</p>	<p>NDC 69238-1050-4 <b>Esomeprazole Magnesium Delayed-Release Capsules, USP</b> <b>20 mg*/Acid Reducer 24 Hour</b> Treats Frequent Heartburn May take 1 to 4 days for full effect One 14-day course of treatment <b>14 Capsules</b></p>  <p>KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.</p>	<p>6MM BLANK FOR GLUE AREA</p> <p>Manufactured by: <b>Amneal Pharmaceuticals Pvt. Ltd.</b> Ahmedabad 382220, INDIA Distributed by: <b>Amneal Pharmaceuticals LLC</b> Bridgewater, NJ 08807</p> 	<p>Non-Varnish Area (For Lot And Exp. Date (26 x 28 mm))</p>	
<p>PEEL BACK FOR ADDITIONAL DRUG FACTS PAGE 10 OF 15</p> <p>NDC 69238-1050-4 <b>Esomeprazole Magnesium Delayed-Release Capsules, USP</b> <b>20 mg*/Acid Reducer 24 Hour</b> Treats Frequent Heartburn May take 1 to 4 days for full effect One 14-day course of treatment <b>14 Capsules</b></p> 	<p>KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION. Do not use if printed foil under capsule is broken. NDC: 69238-1050-4 Mfg. Lot No. 62561541 Rev. 10-2022-03</p> <p>6MM BLANK FOR GLUE AREA</p>	<p><b>Drug Facts</b> (continued) Page 9 of 15</p> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>• adults 18 years of age and older</li><li>• this product is to be used once a day (every 24 hours), every day for 14 days</li><li>• may take 1 to 4 days for full effect</li></ul>	<p><b>Drug Facts</b> (continued) Page 10 of 15</p> <p><b>14-Day Course of Treatment</b></p> <ul style="list-style-type: none"><li>• swallow 1 capsule with a glass of water before eating in the morning</li><li>• take every day for 14 days</li><li>• do not take more than 1 capsule a day</li><li>• swallow whole. Do not crush or chew capsules.</li></ul>	<p><b>Drug Facts</b> (continued) Page 11 of 15</p> <ul style="list-style-type: none"><li>• do not use for more than 14 days unless directed by your doctor</li><li><b>Repeated 14-Day Courses (if needed)</b></li><li>• you may repeat a 14-day course every 4 months</li><li>• do not take for more than 14 days or more often than every 4 months unless directed by a doctor</li></ul>

<p><b>Drug Facts (continued)</b> Page 12 of 15</p> <ul style="list-style-type: none"> <li>children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</li> </ul> <p><b>Other Information</b></p> <ul style="list-style-type: none"> <li>read the directions and warnings before use</li> <li>keep the carton. It contains important information.</li> </ul>	<p><b>Drug Facts (continued)</b> Page 13 of 15</p> <ul style="list-style-type: none"> <li>store at 20° to 25°C (68° to 77°F)</li> <li>Tamper Evident: Do not use if printed safety seal under cap or band around the center of each capsule is broken or missing.</li> </ul> <p><b>Inactive ingredients</b></p> <p>gelatin, hypromellose, magnesium stearate, methacrylic acid copolymer dispersion type C, mono- and di-glycerides,</p>	<p><b>Drug Facts (continued)</b> Page 14 of 15</p> <p>polysorbate 80, sugar sphere (contains- sucrose, corn starch and purified water), sodium lauryl sulphate, talc, triethyl citrate and titanium dioxide.</p> <p>Each capsule is imprinted with blue pharmaceutical ink which contains butyl alcohol, dehydrated alcohol, FD &amp; C Blue # 2 aluminum lake, isopropyl alcohol, propylene glycol, shellac, strong ammonia solution and having one circular</p>	<p><b>Drug Facts (continued)</b> Page 15 of 15</p> <p>line which contains FD &amp; C Blue No. 2 aluminum lake, gelatin and polysorbate 80.</p> <p><b>Questions or comments?</b>  <b>Call toll-free 1-877-835-5472</b>      Mon - Fri 9AM - 5PM EST.      For most recent product information, visit <a href="http://www.amneal.com">www.amneal.com</a></p>
<p><b>Drug Facts</b> Page 1 of 15</p> <p><b>Active ingredient (in each capsule)</b> Purpose</p> <p>Esomeprazole 20 mg.....Acid reducer      ("Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)</p>	<p><b>Drug Facts (continued)</b> Page 2 of 15</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>treats frequent heartburn (occurs 2 or more days a week)</li> <li>not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul>	<p><b>Drug Facts (continued)</b> Page 3 of 15</p> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> • 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.</p>	<p><b>Drug Facts (continued)</b> Page 4 of 15</p> <p><b>Do not use if you have</b></p> <ul style="list-style-type: none"> <li>trouble or pain swallowing food, vomiting with blood, or bloody or black stools</li> <li>heartburn with <b>lightheadedness, sweating or dizziness</b></li> <li>chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> </ul>
<p><b>Drug Facts (continued)</b> Page 5 of 15</p> <ul style="list-style-type: none"> <li>frequent chest pain</li> </ul> <p>These may be signs of a serious condition. See your doctor.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>frequent wheezing, particularly with heartburn</li> </ul>	<p><b>Drug Facts (continued)</b> Page 6 of 15</p> <ul style="list-style-type: none"> <li>unexplained weight loss</li> <li>nausea or vomiting</li> <li>stomach pain</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>taking a prescription drug. Acid reducers may interact with certain prescription drugs.</li> </ul>	<p><b>Drug Facts (continued)</b> Page 7 of 15</p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>your heartburn continues or worsens</li> <li>you need to take this product for more than 14 days</li> <li>you need to take more than 1 course of treatment every 4 months</li> <li>you get diarrhea</li> <li>you develop a rash or joint pain</li> </ul>	<p><b>Drug Facts (continued)</b> Page 8 of 15</p> <p><b>If pregnant or breast-feeding, ask a health professional before use.</b></p> <p><b>Keep out of the reach of children.</b>      In case of overdose, get medical help or contact a Poison Control Center right away.</p>

**NDC 69238-1050-3**

**Esomeprazole Magnesium Delayed-Release Capsules, USP /Acid Reducer (OTC)**


**20 mg**

**42 Capsules (Carton Pack)**

**Amneal Pharmaceuticals LLC**

Non Varnish Area for Lot # and Exp. 135 X 25 mm

3 69238 10503 2



**Tips for Managing Heartburn**

- Acid foods or drinks that are more likely to cause heartburn, such as red, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some apples, 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 printed foil under cap is broken or missing.**

Mfg. Lic. No. 025/1941

Manufactured by:  
Amneal Pharmaceuticals Pvt. Ltd.  
Amnabad 38220, INDIA

Distributed by:  
Amneal Pharmaceuticals LLC  
Springer, NJ 08927

Rev. 10-2022-03

NDC 69238-1050-3

**Treats Frequent Heartburn**


**Esomeprazole Magnesium Delayed-Release Capsules, USP**

**20 mg \* /Acid Reducer 24 Hour**

May take 1 to 4 days for full effect

42 Capsules

Three 14-Day Courses of Treatment



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

**Drug Facts**

**Active ingredient Purpose**

Esomeprazole 20 mg..... Acid reducer  
 ("Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate")

**Uses**

- treats frequent heartburn (occurs 2 or more days a week)
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**Warnings**

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- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness

**Drug Facts (continued)**

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These may be signs of a serious condition. See your doctor.

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- nausea or vomiting
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**Drug Facts (continued)**

**Keep out of the 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 (only 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
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**Repeated 14-Day Courses (if needed)**

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**Drug Facts (continued)**

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**Questions or comments?**  
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**ESOMEPRAZOLE MAGNESIUM**  
 esomeprazole magnesium capsule, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69238-1050
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ESOMEPRAZOLE MAGNESIUM</b> (UNII: R6DXU4WAY9) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>CAPRYLIC/CAPRIC MONO/DI-GLYCERIDES</b> (UNII: U72Q2I8C85)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B710)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	AMNEAL1050
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69238-1050-9	2 in 1 BLISTER PACK	06/05/2019	

1	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69238-1050-8	3 in 1 BLISTER PACK	06/05/2019	
2	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69238-1050-5	1 in 1 CARTON	06/05/2019	
3	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69238-1050-2	2 in 1 CARTON	06/05/2019	
4	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69238-1050-3	3 in 1 CARTON	06/05/2019	
5	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:69238-1050-1	1 in 1 BLISTER PACK	06/05/2019	
6	NDC:69238-1050-4	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	06/05/2019	

**Labeler** - Amneal Pharmaceuticals NY LLC (123797875)

## Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals Private Limited		915076126	analysis(69238-1050) , label(69238-1050) , manufacture(69238-1050) , pack(69238-1050)

Revised: 12/2023

Amneal Pharmaceuticals NY LLC