

**ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release**  
**Amneal Pharmaceuticals NY LLC**

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

***Drug Facts***

<b><i>Active ingredient (in each capsule)</i></b>	<b><i>Purpose</i></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

**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 diglycerides, 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 14 Capsules</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><small>SEE BACK FOR ADDITIONAL DRUG FACTS</small></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 14 Capsules</p>	<p>KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.</p> <p><small>Do not take this product if you are allergic to esomeprazole, magnesium, or any of the other ingredients. See the back of the carton for a complete list of ingredients.</small></p> <p><small>NDC 69238-1050-4                  NDC 69238-1050-5                  NDC 69238-1050-6</small></p>	<p><b>Drug Facts (continued)</b> 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 (continued)</b> 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 (continued)</b> 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><b>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</b></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 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>                  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>                  Call toll-free 1-877-835-5472                  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>                  Esomeprazole 20 mg.....Acid reducer                  (*Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)</p> <p><b>Purpose</b></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</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 lightheadedness, sweating or dizziness</li> </ul>	<p><b>Drug Facts (continued)</b> Page 4 of 15</p> <ul style="list-style-type: none"> <li>chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>frequent chest pain</li> </ul> <p>These may be signs of a serious condition. See your doctor.</p>	<p><b>Drug Facts (continued)</b> Page 5 of 15</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> <li>unexplained weight loss</li> <li>nausea or vomiting</li> </ul>
--	---	--	---	---

<p><b>Drug Facts (continued)</b> Page 6 of 15</p> <ul style="list-style-type: none"> <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>	<p>SEE BACK FOR ADDITIONAL DRUG FACTS</p> <p>9MM BLANK FOR GLUE AREA</p>
---	--	---	--

NDC 69238-1050-3

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

20 mg

42 Capsules (Carton Pack)

Amneal Pharmaceuticals LLC



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:69238-1050-1	1 in 1 BLISTER PACK	06/05/2019	
1	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69238-1050-9	2 in 1 BLISTER PACK	06/05/2019	
2	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69238-1050-8	3 in 1 BLISTER PACK	06/05/2019	
3	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69238-1050-5	1 in 1 CARTON	06/05/2019	
4	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69238-1050-2	2 in 1 CARTON	06/05/2019	
5	NDC:69238-1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:69238-1050-3	3 in 1 CARTON	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)