

**ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release**  
**INNOVUS PHARMACEUTICALS, INC.**

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**Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg\***

***Drug Facts***

***Active ingredient (in each capsule)***

\*Esomeprazole 20 mg  
(Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium dihydrate 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
- 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. (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***

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F)

- Meets USP dissolution test 2

### ***Inactive ingredients***

colloidal silicon dioxide, FD&C blue no.1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion, mono and di glycerides, polysorbate 80, propylene glycol, shellac, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains liquid glucose, starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide.

### ***Questions or comments?***

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed By:

**Innovus Pharmaceuticals, Inc.**

Englewood, CO 80112

[www.crclehealth.com](http://www.crclehealth.com)

Made in India

Code: TS/DRUGS/22/2009

### **PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsule Container Label)**

NDC 57483-225-14

**C'rcle™ Heartburn Relief**

EsomepraCare®

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

20 mg\* / Acid Reducer

See new  
warning  
information

**24  
hour  
Treats Frequent  
Heartburn**

### **14 CAPSULES**

One 14-day course of treatment May  
take 1 to 4 days for full effect

# Top Ply

NDC 57483-225-14

**Heartburn Relief**  
EsomepraCare®  
**Esomeprazole Magnesium  
Delayed-Release Capsules USP**  
20 mg\* / Acid Reducer

**14 CAPSULES**  
One 14-day course of treatment  
May take 1 to 4 days for full effect

See new warning information

**24 hour Treats Frequent Heartburn**

**Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.**

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

Distributed By:  
Innovus Pharmaceuticals, Inc.  
Englewood, CO 80112  
www.crclehealth.com

Made in India Code: TS/DRUGS/22/2009  
100720-1 01.23

**Active ingredient (in each capsule)**  
\*Esomeprazole 20 mg.....  
(Each delayed-release capsule corresponds to 21.75 mg esomeprazole magnesium dihydrate 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

P1432285 LM-5094

Lift Here

No Varnish

## Top Ply (Page #1)

**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 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

P1432285 LM-5094

**HINGE**

## Back of Top Ply (Page #2)

# Bottom Ply

**HINGE**

■ 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 20-25°C (68-77°F) ■ Meets USP dissolution test 2. **Inactive ingredients** colloidal silicon dioxide, FD&C blue no. 1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion, mono and di glycerides, polysorbate 80, propylene glycol, shellac, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains liquid glucose, starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide. **Questions or comments?** call 1-855-274-4122 (Monday - Friday 8:30 AM to 5:00 PM EST)

P1432285 LM-5094

## Base (Page #3) Bottom Ply

# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (42 Capsule Container Carton)

Compare to active ingredient of Nexium® 24 HR†  
**C'rcle™**  
**Heartburn Relief**  
**EsomepraCare®**

NDC 57483-225-42

**Esomeprazole Magnesium**  
**Delayed-Release Capsules USP**  
 20 mg\* / Acid Reducer

See new warning information  
**24**  
**hour**  
**Treats Frequent Heartburn**

**42 CAPSULES**  
**TRIPLE PACK 3X14 count bottles inside**  
 Three 14-day courses of treatment  
 May take 1 to 4 days for full effect

**GLUE - NO COATING**

**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.
- trouble swallowing, 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.
- pregnant or breast-feeding, ask a health professional before use.
- you develop a rash or joint pain

**Stop use and ask a doctor if:**

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you get diarrhea
- you develop a rash or joint pain

**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

**Drug Facts (continued)**

**Warnings**

- 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.
- contains important information.
- keep away from heat and moisture. Store at 20-25°C (68-77°F).
- Keep away from children.

**Inactive Ingredients**

colloidal silicon dioxide, FD&C blue no. 1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid and ethyl acrylate copolymer dispersion, mono and diglycerides, polyethylene glycol, polyethylene glycol, sodium lauryl sulfate, strong ammonia solution, sugar spheres (which contains liquid glucose, starch (maize) and sucrose), talc, titanium dioxide, triethyl citrate and yellow iron oxide.

**Questions or comments? Call 1-866-274-4122 (Monday - Friday 9:00 AM to 5:00 PM EST).**

**Do not use if seal imprinted with SEAL for YOUR PROTECTION under the bottle cap is broken or missing.**

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

**Tip for Managing Heartburn**

- Avoid foods or drinks that are most 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 by mouth.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Stand the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

Distributed By: **Nivves Pharmaceuticals, Inc.**  
 Englewood, CO 80112  
 www.crclehealth.com

Made in India  
 Code: 505000222000  
 † This product is not manufactured or distributed by Pfizer Inc., owner of the registered trademark of Nexium® 24 HR.

Compare to active ingredient of Nexium® 24HR†

NDC 57483-225-42

**C'rcle.**

**Heartburn Relief**  
 EsomepraCare®  
**Esomeprazole Magnesium**  
**Delayed-Release Capsules USP**  
 20 mg / Acid Reducer

**42 CAPSULES**  
 TRIPLE PACK 3X14 count bottles inside  
 Three 14-day courses of treatment  
 May take 1 to 4 days for full effect

**24**  
**hour**  
**Treats Frequent Heartburn**

**Drug Facts**

**Active Ingredient (in each capsule)**

Esomeprazole 20 mg ..... Acid reducer  
 Each delayed-release capsule corresponds to 17.75 mg esomeprazole magnesium dihydrate USP

**Purpose**

to treat frequent heartburn (occurs 2 or more days a week)

**Warnings**

- Do not use if you are allergic to esomeprazole.
- Esomeprazole may cause severe skin reactions.
- Symptoms may include: skin rash/itching, blisters, or rash.
- If an allergic reaction occurs, stop use and seek medical help right away.

**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

**Interactions with:** heartburn with high blood pressure, sweating or dizziness

**Check pain or shoulder pain with:** stiffness of breast, sweating, pain spreading to arms, neck or shoulders, or light-headedness

**Frequent chest pain:** There may be signs of a serious condition. See your doctor.

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P1051119 LN-5095

Lot:  
 Expiry: **NVZ**

# ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57483-225
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ESOMEPRAZOLE MAGNESIUM DIHYDRATE</b> (UNII: 36H71644EQ) (ESOMEPRAZOLE - UNII:N3PA6559FT)	ESOMEPRAZOLE	20 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM CARBONATE</b> (UNII: 0E53J927NA)	
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>DEXTRROSE, UNSPECIFIED FORM</b> (UNII: IY9XDZ35W2)	
<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>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	

## 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>	I81
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57483-225-42	3 in 1 CARTON	05/25/2023	
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	ANDA209339	05/25/2023	

**Labeler** - INNOVUS PHARMACEUTICALS, INC. (962507187)**Registrant** - Aurohealth LLC (078728447)**Establishment**

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(57483-225) , MANUFACTURE(57483-225)

Revised: 5/2023

INNOVUS PHARMACEUTICALS, INC.