

ESOMEPRAZOLE MAGNESIUM - esomeprazole magnesium capsule, delayed release

Better Living Brands LLC

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

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 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?

1-888-723-3929

BETTER LIVING BRANDS LLC
 P.O. BOX 99, PLEASANTON, CA 94566-0009
 1-888-723-3929/www.betterlivingbrandsLLC.com

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsules Container Label)

NDC XXXXX-XXX-XX

Capsules

Signature Care™

Quality Guaranteed

24 Hours

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP 20 mg*

Acid Reducer

Treats frequent heartburn

May take 1 to 4 days for full effect

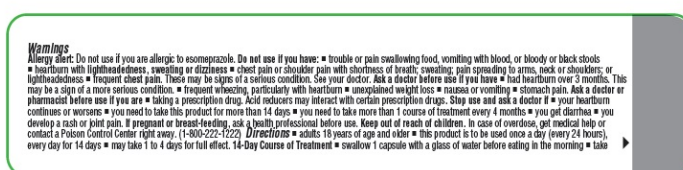
14 Capsules

One 14-day course of treatment

Top Ply



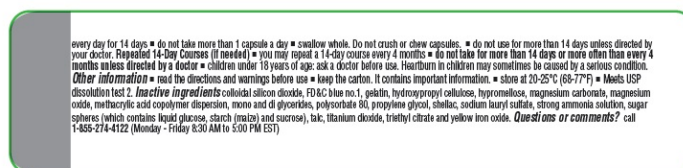
Top Ply
(Page #1)



Back of Top Ply
(Page #2)

Bottom Ply

Base
(Page #3)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 20 mg (14 Capsules Container Carton Label)

COMPARE TO Nexium® 24 HR
Active ingredient*
Capsules
1 Bottle Inside
NDC XXXXX-XXX-XX
Signature Care™

Quality Guaranteed
24 Hours
Esomeprazole Magnesium
DELAYED-RELEASE CAPSULES USP 20 mg*
Acid Reducer
Treats frequent heartburn

May take 1 to 4 days for full effect
SEE NEW WARNING INFORMATION
14 Capsules
One 14-day course of treatment



Esomeprazole Magnesium
DELAYED-RELEASE CAPSULES USP
20 mg*

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.

Scan here for more information

Drug Facts (continued)

- 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)

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Drug Facts (continued)

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Inactive ingredients colloidal silicon dioxide, FD&C blue no. 1, gelatin, hydroxypropyl cellulose, hypromellose, magnesium carbonate, magnesium oxide, methacrylic acid copolymer dispersion, mono and di glycerides, poly sorbate 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)

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.

#This product is not manufactured or distributed by Pfizer Inc., owner of the registered trademark of Nexium® 24 HR

DISTRIBUTED BY:
 BETTER LIVING BRANDS LLC
 P.O. BOX 99, PLEASANTON
 CA 94566-0099
 1-888-723-3829
 www.betterlivingbrandsLLC.com
 Made in India
 Code: TS/DRUS222009

OUR PROMISE
 QUALITY & SATISFACTION
100% GUARANTEED
 OR YOUR MONEY BACK.

Capsules
 1 Bottle Inside

Compare to Nexium® 24 HR active ingredient*
 NDC XXXXX-XXX-XX

← 1 →

Signature Care™
 Quality Guaranteed

24 HOUR
Esomeprazole Magnesium
 DELAYED-RELEASE CAPSULES USP 20 mg*
 Acid Reducer

Treats frequent heartburn

May take 1 to 4 days for full effect

SEE NEW WARNING INFORMATION

Actual Size

14 CAPSULES
 One 14-day course of treatment

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Warnings
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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 ▶

3 21130 27702 6

Lot: N.C. Area
 Expiry:

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
AMMONIA (UNII: 5138Q19F1X)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	I81
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:21130-100-05	1 in 1 CARTON	07/24/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-100-08	2 in 1 CARTON	07/24/2019	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:21130-100-10	3 in 1 CARTON	07/24/2019	
3		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	07/24/2019	

Labeler - Better Living Brands LLC (009137209)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(21130-100) , MANUFACTURE(21130-100)

Revised: 4/2024

Better Living Brands LLC