

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release

BETTER LIVING BRANDS, LLC

718T_Albertsons_21130-718_Esomeprazole magnesium delayed release capsules USP, 20mg

Drug Facts

Active ingredient (in each capsule)

Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)

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 include:

-skin reddening
-blisters
-rash

If an allergic reaction occurs, stop use and seek medical attention 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 (1-800-222-1222) 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

1. swallow 1 capsule with a glass of water before eating in the morning
2. take every day for 14 days
3. do not take more than 1 capsule a day
4. swallow whole. Do not crush or chew capsules.
5. do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

1. you may repeat a 14-day course every 4 months
2. **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)

Inactive ingredients black iron oxide, eudragit, FD&C blue 1, FD&C red 3, ferric oxide yellow, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, polysorbate 80, potassium hydroxide, shellac, simethicone, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate.

Questions or comments?1-877-290-4008

Coating/
Print Omit Area

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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 over-the-counter herbs and vegetables.
● Eat slowly and do not eat just before bedtime.
● Do not eat late at night or just before bedtime.
● Do not lie flat or bend over soon after eating.
● Place the head of your bed 6 to 8 inches from the floor, padding around your stomach.
● If you are overweight, lose weight.
● If you smoke, quit smoking.
Clinically Proven to Treat Frequent Heartburn



Quality Guaranteed

24 HOUR
Esomeprazole Magnesium
DELAYED-RELEASE CAPSULES USP, 20 mg

NDC 2130-718-82
Capsules

Compare to Nexium® 24 HR active ingredient!

WINDOW

WINDOW



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

Actual Size
Treats frequent heartburn
May take 1 to 4 days for full effect

SEE NEW WARNING INFORMATION

28 CAPSULES
Two 14-day courses of treatment

Actual Size 2 bottles inside



TAMPER EVIDENT. DO NOT USE IF THE IMPRINTED SEAL UNDER BOTTLE CAP OR BAND AROUND THE CENTER OF EACH CAPSULE IS BROKEN OR MISSING



Lot No.:
Exp. Date:



RD 23168 5934
This product is not manufactured or distributed by Helsion group of companies, owner of the registered trademark Nexium® 24HR
DISTRIBUTED BY:
SETTEL LANGE BRANDS LLC
P.O. BOX 99
PLEASANTON, CA 94566-0099
1-888-725-2829
Made in India
7187 0623



Coating/
Print Omit Area

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Clinically Proven to Treat Frequent Heartburn



Quality Guaranteed

24 HOUR
Esomeprazole Magnesium
DELAYED-RELEASE CAPSULES USP, 20 mg

NDC 2130-718-41
Capsules

Compare to Nexium® 24 HR active ingredient!

WINDOW

WINDOW

WINDOW



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Acid Reducer

Actual Size
Treats frequent heartburn
May take 1 to 4 days for full effect

SEE NEW WARNING INFORMATION

42 CAPSULES
Three 14-day courses of treatment



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Lot No.:
Exp. Date:



RD 23168 5934
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Adhesive Area

Drug Facts (continued)

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1-877-290-4008

DISTRIBUTED BY:

BETTER LIVING BRANDS, LLC

P.O. BOX 99

PLEASANTON, CA 94566-0099

41-888-723-3929

Made in India

7181 0623

SS934

OR IT'S ON US*



Drug Facts (continued under label)

Lot No.:
Exp. Date:
PEEL HERE

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Acid reducer
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Active ingredient (in each capsule)

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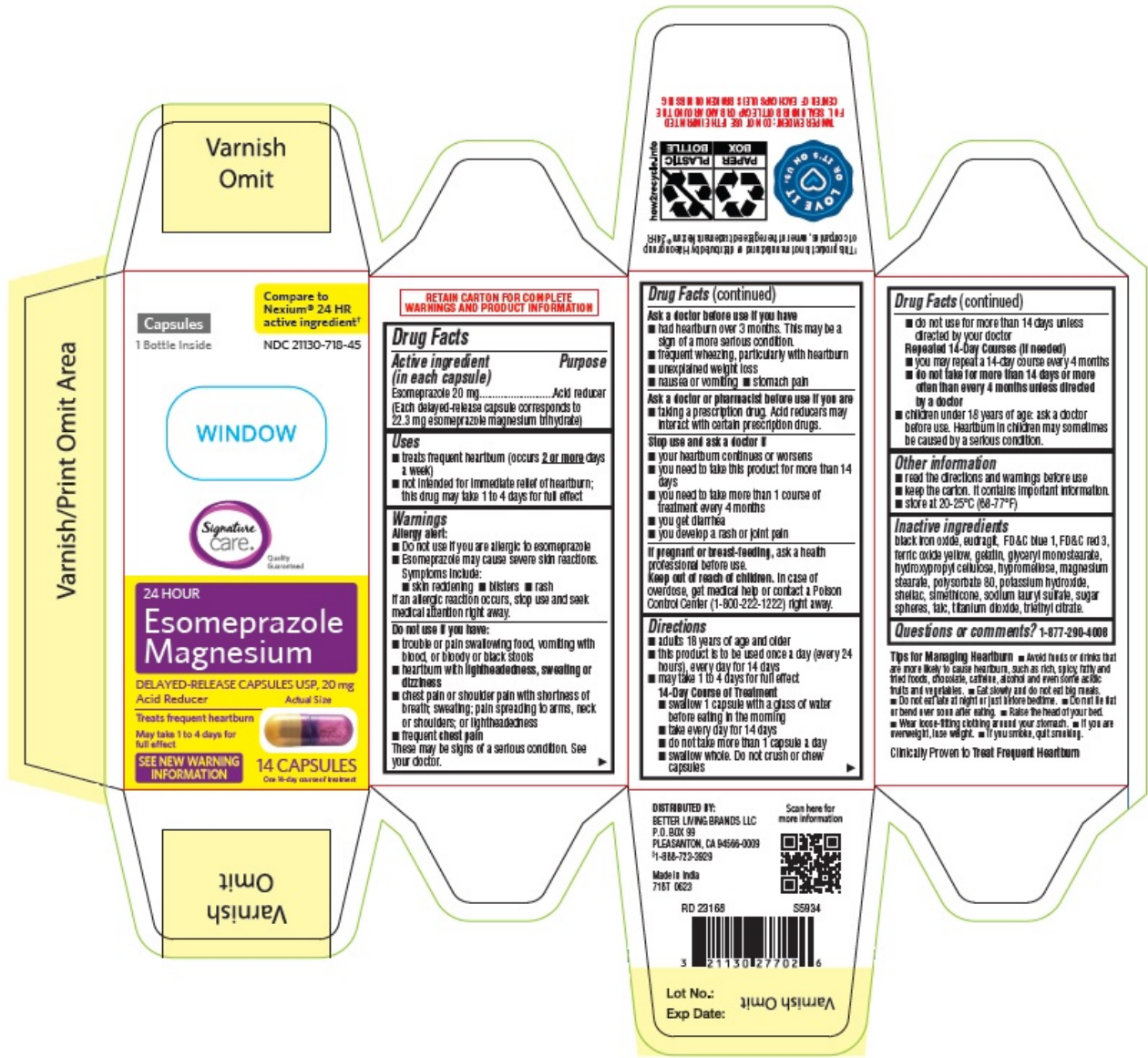
TAMPER EVIDENT: DO NOT USE IF THE IMPRINTED FOIL SEAL UNDER BOTTLE CAP OR BAND AROUND THE CENTER OF EACH CAPSULE IS BROKEN OR MISSING

NDC 21130-718-45



24 HOUR 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



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-718
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
DIMETHICONE (UNII: 92RU3N3Y1O)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	purple (PURPLE (golden cap and violet transparent body having light violet to violet colour band))	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-718-45	1 in 1 CARTON	10/20/2023	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-718-41	3 in 1 CARTON	10/20/2023	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:21130-718-82	2 in 1 CARTON	11/13/2023	
3		14 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217264	10/20/2023	

Labeler - BETTER LIVING BRANDS, LLC (009137209)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(21130-718)

Revised: 11/2023

BETTER LIVING BRANDS, LLC