# ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release

BETTER LIVING BRANDS, LLC

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# 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





#### RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts (continued)

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Compare to Nexium® 24 HR active ingredient®

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Signature Care。

NDC 21130-718-82

24 HOUR Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP, 20 mg Acid Reducer

28 CAPSULES

A sec.

Actual Size

2 Bottles inside

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Exp. Date:



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#### RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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Questions or comments? 1477-290-4008



## Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP, 20 mg

Compare to Nexium® 24 HR active ingredient†

Capsules

WINDOW

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SEE NEW WARNING

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP, 20 mg
Acid Reducer

WINDOW

42 CAPSULES

WINDOW

Print Omit Area Coating/





This product is not manufactured or distributed by Hales group at companies owned of the registered but email: Necture 1946. 
BETTER LAWRE BRANCE LLC P.O. 607.09
P.O. 607.09
P.C. 6587010 J.C. 44551-1889
11-888-723-9009

Coating/Print Omit Area Exp. Date:



3 Bottles inside

# Adhesive Area

#### DISTRIBUTED BY: BETTER LIVING BRANDS LLC P. O. BOX 99 PLEASANTON, CA 94566-0009 41-888-723-3929 Made in India 718T 0623 S5934 OR IT'S ON US LOVE Questions or comments? read the directions and warnings before use keep the car ton. It contains important information. store at 20-25°C (68-77°F) Other information by a doctor I children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition. hours), every day for 14 days may take 1 to 4 days for full effect do not use for more than 14 days unless directed by your doctor Repeated 14-Day Courses (if needed) do not take for more than 14 days or more Take every day for 14 days do not take more than 1 capsule a day swallow whole. Do not crush or chew 4-Day Course of Treatment often than every 4 months unless directed you may repeat a 14-day course every 4 swallow 1 capsule with a glass of water before eating in the morning BD 53 168



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Drug Facts (continued under label)

adults 18 years of age and older
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Directions

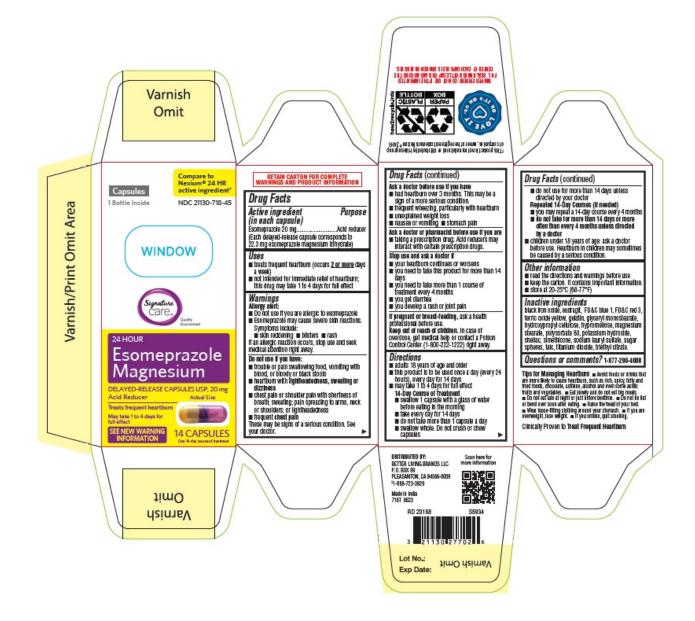
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

If an allergic reaction occurs, stop use and seek medical attention right away.

rash

Drug Facts (continued)

Lot No.: Exp Date:



## **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: 92RU3N3Y10)	
FERROSOFERRIC 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: 2300U9XXE4)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SHELLAC (UNII: 46N107B710)	
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: EX43802MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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	<b>Business Operations</b>	
MARKSANS PHARMA LIMITED		925822975	manufacture(21130-718)	

Revised: 11/2023 BETTER LIVING BRANDS, LLC