

ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release
BETTER LIVING BRANDS LLC.

Albertsons ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE 20 MG MINI

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 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 (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

- 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)

Inactive ingredients black iron oxide, corn starch, D&C red 27 aluminum lake, 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, sucrose, talc, titanium dioxide, triethyl citrate

Questions or comments? Call **1-877-290-4008**

Drug Facts (continued)

every day for 14 days
 may take 1 to 4 days for full effect

14-Day Course of Treatment
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Questions or comments?

1-877-290-4008

DISTRIBUTED BY:
 BETTER LIVING BRANDS LLC
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 41-888-723-3929

Made in India
 7251 0723
 55934

LOVE IT OR IT'S ON US



Adhesive Area

Inside

1/16" Margin



NDC 21130-257-45

Quality Guaranteed

Mini Capsules 24 HOUR

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP, 20 mg Acid Reducer

Treats frequent heartburn **14 MINI CAPSULES**
 May take 1 to 4 days for full effect. *One 14-day course of treatment*

RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

Drug Facts

Active ingredient (in each capsule)
 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
 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.
 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)

Drug Facts (continued under label)

Lot No.: _____

Exp. Date: _____

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Quality Guaranteed

Mini Capsules 24 HOUR

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP, 20 mg

SEE NEW WARNING INFORMATION

WINDOW

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WINDOW

Compare to Nexium® 24 HR Clear Minis™ active ingredient*

WINDOW

WINDOW

WINDOW

Mini Capsules 24 HOUR

Esomeprazole Magnesium

DELAYED-RELEASE CAPSULES USP, 20 mg Acid Reducer

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

42 MINI CAPSULES
Three 14-day courses of treatment

Actual Size 3 Bottles Inside



*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

Coating/
Print Omit Area

Scan here for more information



RD 23182 55904



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This product is not manufactured or distributed by Hainan group of companies, owner of the registered trademark Nexium® 24HR Clear Minis.

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Made in India
 7251 0723

Lot No.: _____

Exp. Date: _____

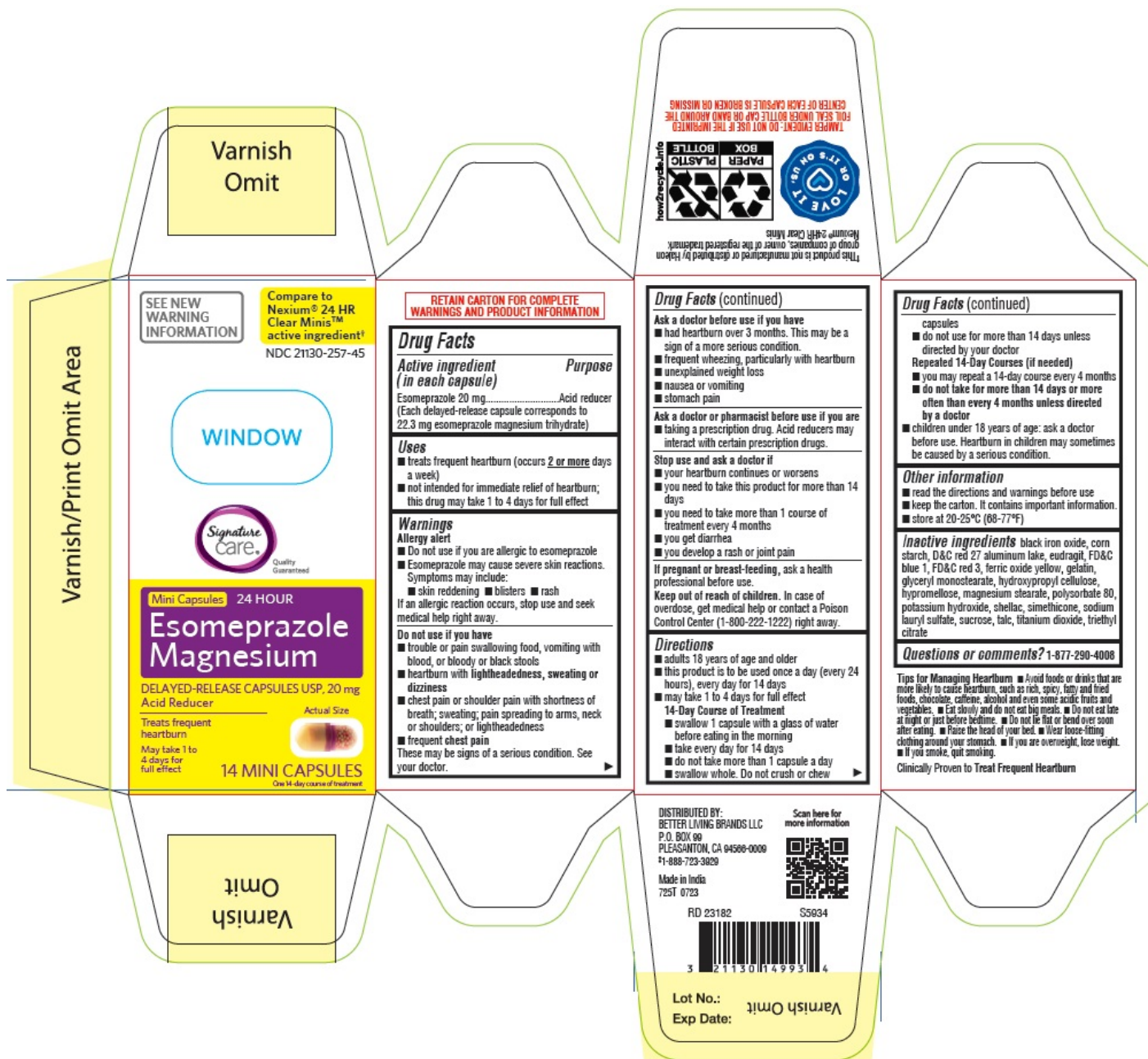
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ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21130-257 |
| 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 |
|---|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) | |
| TALC (UNII: 7SEV7J4R1U) | |
| SHELLAC (UNII: 46N107B71O) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| SUCROSE (UNII: C151H8M554) | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |
| FD&C RED NO. 3 (UNII: PN2ZH5LOQY) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX) | |
| MAGNESIUM STEARATE (UNII: 70097M6I3O) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| GELATIN (UNII: 2G86QN327L) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |

Product Characteristics

| | | | |
|-----------------|--|---------------------|----------|
| Color | yellow (golden yellow opaque cap, transparent body, light violet to violet color band) | Score | no score |
| Shape | CAPSULE | Size | 11mm |
| Flavor | | Imprint Code | 112 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:21130-257-45 | 1 in 1 CARTON | 04/29/2024 | |
| 1 | | 14 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:21130-257-41 | 3 in 1 CARTON | 04/29/2024 | |
| 2 | | 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 | ANDA217264 | 04/29/2024 | |
|------|------------|------------|--|

Labeler - BETTER LIVING BRANDS LLC. (009137209)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| MARKSANS PHARMA LIMITED | | 925822975 | manufacture(21130-257) |

Revised: 4/2024

BETTER LIVING BRANDS LLC.