ESOMEPRAZOLE- esomeprazole capsule, delayed release
Sun Pharmaceutical Industries, Inc.

Drug Facts

Active ingredient (in each capsule)

Esomeprazole 20 mg (Each delayed-release capsule contains 22.3 mg esomeprazole magnesium trihydrate)

Purpose

Acid reducer

Use

- 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. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use.
- Store at 20°C to 25°C (68°F to 77°F). [See USP controlled room temperature.]
- keep the carton. It contains important information.

Inactive Ingredients

FD & C blue no 1, FD & C red no 3, ferrosoferric oxide, gelatin, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer dispersion, mono and di glycerides, polysorbate 80, potassium hydroxide, propylene glycol, shellac, sugar spheres (corn starch and sucrose), talc, titanium dioxide and triethyl citrate.

Questions?

Call toll-free weekdays 8:30 AM to 5 PM EST at **1-800-818-4555.**

TAMPER-EVIDENT FEATURES: Do not use if seal under bottle cap imprinted with *"SEALED for YOUR PROTECTION"* or blue band around center of each capsule is broken or missing.

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.

Manufactured by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

Distributed by:

Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512

1019

Package/Label Principal Display Panel

NDC 63304-740-14

Treats Frequent Heartburn

Esomeprazole Magnesium Delayed-Release

Capsules USP,

20 mg

Acid Reducer

May take 1 to 4 days for full effect

ohm®

14 CAPSULES

One 14-day course of treatment

Principal Display Panel

NDC 63304-740-14

Treats Frequent Heartburn

Esomeprazole Magnesium Delayed-Release Capsules USP,

20 mg

Acid Reducer

May take 1 to 4 days for full effect

ohm®

1 X 14 Count Bottle Inside

14 CAPSULES

One 14-day course of treatment

ESOMEPRAZOLE

esomeprazole capsule, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63304-740
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**

FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	RG;50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63304-740-44	3 in 1 CARTON	11/30/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63304-740-27	2 in 1 CARTON	11/30/2019	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:63304-740-14	1 in 1 CARTON	11/30/2019	
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	ANDA212866	11/30/2019	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Registrant - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations

Ohm Laboratories Inc.		184769029	MANUFACTURE(63304-740)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		918591058	API MANUFACTURE(63304-740)

Revised: 5/2020 Sun Pharmaceutical Industries, Inc.