NEXIUM 24HR- esomeprazole magnesium tablet
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

Active ingredient (in each tablet)

Esomeprazole 20 mg (Each delayed-release tablet 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

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.

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 tablet with a glass of water before eating in the morning
  - take every day for 14 days
  - do not take more than 1 tablet a day
  - swallow whole. Do not crush or chew tablets.
  - 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

corn starch, crospovidone, D&C red no. 27 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, mica, microcrystalline cellulose, paraffin, polyethylene glycol, polysorbate 80, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triethyl citrate

Questions or comments?

call toll-free weekdays 9 AM to 5 PM EST at **1-866-226-1600**

Made in France

For most recent product information, visit
www.Nexium24HR.com

Do Not Use if seal under bottle cap imprinted with “SEALED for YOUR PROTECTION” is broken or

missing.

Additional Information

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

PRINCIPAL DISPLAY PANEL

NDC 0573-2451-42

Nexium®

esomeprazole magnesium

delayed-release tablets

20 mg/acid reducer

24HR

See new warning information

Treats Frequent Heartburn

Tablets

May take 1 to 4 days for full effect

42 TABLETS

Three 14-day courses of treatment

PAA114854 Front Carton

NEXIUM 24HR

esomeprazole magnesium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-2451
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)	
CROSPOVIDONE (120 .MU.M) (UNII: 68401960MK)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	PURPLE	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	N;20;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2451-14	1 in 1 CARTON	02/06/2016	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-2451-42	3 in 1 BLISTER PACK	02/06/2016	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-2451-28	2 in 1 CARTON	07/01/2021	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-2451-43	3 in 1 PACKAGE	07/01/2021	
4		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
NDA	NDA207920	02/06/2016	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
Wyeth Pharmaceuticals Company		829390975	ANALYSIS(0573-2451) , LABEL(0573-2451) , MANUFACTURE(0573-2451) , PACK(0573-2451)

Revised: 7/2021 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC