

NEXIUM 24HR- esomeprazole magnesium capsule, delayed release
NEXIUM 24HR CLEARMINIS- esomeprazole magnesium capsule, delayed release
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

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 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 Repeated 14-Day Courses (if needed)

- 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
 - 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 (Nexium 24HR Capsules)

corn starch, D&C red no. 28, FD&C blue no. 1, FD&C red no. 40, ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, pharmaceutical ink, polysorbate 80, sucrose, talc, titanium dioxide, triethyl citrate

Inactive Ingredients (Nexium 24HR ClearMinis)

carmine, corn starch, FD&C blue no. 2, FD&C blue no. 2 aluminum lake, FD&C red no. 3, FD&C red no. 40, ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, pharmaceutical ink, polysorbate 80, sucrose, talc, titanium dioxide, triethyl citrate

Questions or comments?

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

Additional Information

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

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

or yellow band around the 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.

Distributed by: GSK Consumer Healthcare,

Warren, NJ 07059

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

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PRINCIPAL DISPLAY PANEL

NDC 0573-2450-14

See new warning information

Treats Frequent Heartburn

Nexium®

24HR

esomeprazole magnesium

delayed-release capsules
20 mg/acid reducer

Capsules

May take 1 to 4 days for full effect

**14
CAPSULES**

One 14-day course of treatment

000078381 Front Carton



PRINCIPAL DISPLAY PANEL

NDC 0573-2452-14

See new warning information

Treats Frequent Heartburn

Nexium®

24HR

esomeprazole magnesium
delayed-release capsules
20 mg/acid reducer

Clear Minis™

May take 1 to 4 days for full effect

14

CAPSULES

One 14-day course of treatment

000078392 Front Carton



NEXIUM 24HR

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-2450
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)	
D&C RED NO. 28 (UNII: 7671P0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROXYPROPYL CELLULOSE (160000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	PURPLE (amethyst)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	NEXIUM;20;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2450-14	1 in 1 CARTON	05/27/2014	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-2450-15	1 in 1 BLISTER PACK	05/27/2014	12/31/2022
3		14 in 1 BOTTLE; Type 0: Not a Combination		

4		Product		
3	NDC:0573-2450-28	2 in 1 CARTON	05/27/2014	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-2450-42	3 in 1 CARTON	05/27/2014	
4		14 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0573-2450-43	3 in 1 BLISTER PACK	05/27/2014	
5		14 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0573-2450-44	3 in 1 CARTON	05/27/2014	
6		14 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0573-2450-17	1 in 1 CARTON	05/27/2014	04/29/2016
7		14 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0573-2450-02	1 in 1 CARTON	10/31/2014	
8		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA204655	05/27/2014	

NEXIUM 24HR CLEARMINIS

esomeprazole magnesium capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-2452
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
CARMINIC ACID (UNII: CID8Z8N95N)	
STARCH, CORN (UNII: O8232NY3SJ)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FERRIC OXIDE RED (UNII: 1K09F3G675)
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)
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)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
SUCROSE (UNII: C151H8M554)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	PURPLE (amethyst) , YELLOW	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	NEXIUM;20;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2452-14	1 in 1 CARTON	03/01/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-2452-42	3 in 1 CARTON	03/01/2017	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0573-2452-43	3 in 1 BLISTER PACK	03/01/2017	08/31/2017
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-2452-02	1 in 1 CARTON	03/01/2017	
4		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA204655	03/01/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Wyeth Pharmaceuticals Company		829390975	ANALYSIS(0573-2450, 0573-2452) , LABEL(0573-2450, 0573-2452) , MANUFACTURE(0573-2450, 0573-2452) , PACK(0573-2450, 0573-2452)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0573-2450, 0573-2452) , LABEL(0573-2450, 0573-2452) , MANUFACTURE(0573-2450, 0573-2452) , PACK(0573-2450, 0573-2452)

Revised: 1/2023

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC