



DRUG MARKET WITHDRAWAL

Esomeprazole Magnesium Delay Released Capsules USP 20 mg
(NDC: For 30'S : 68462-390-30 , For 90'S :68462-390-90 and For
1000'S: 68462-390-10 and 40 mg For 30'S : 68462-391-30, 90'S :
68462-391-90 and 1000'S : 68462-391-10

November 30, 2023

Dear Customer,

This is to inform you of a voluntary market withdrawal to wholesaler level involving the following:

Esomeprazole Magnesium Delay Released Capsules USP 20 mg and 40 mg (Capsule)

Sr. no	NDC	Batch	Pack Size	Expiry Date
1.	68462-390-30	17212405	30 capsules	Nov-2023
2.	68462-390-90	17212405	90 capsules	Nov-2023
3.	68462-391-30	17212406	30 capsules	Nov-2023
4.	68462-391-90	17212406	90 capsules	Nov-2023
5.	68462-391-10	17220001	1000 capsules	Nov-2023
6.	68462-391-30	17220001	30 capsules	Nov-2023
7.	68462-390-30	17220030	30 capsules	Nov-2023
8.	68462-391-30	17220031	30 capsules	Nov-2023
9.	68462-390-30	17220686	30 capsules	Feb-2024
10.	68462-391-30	17220685	30 capsules	Feb-2024
11.	68462-391-10	17220685	1000 capsules	Feb-2024
12.	68462-391-90	17220785	90 capsules	Feb-2024
13.	68462-390-10	17220686	1000 capsules	Feb-2024
14.	68462-390-90	17220784	90 capsules	Feb-2024
15.	68462-391-30	17220913	30 capsules	Feb-2024
16.	68462-390-30	17220912	30 capsules	Feb-2024
17.	68462-390-30	17221178	30 capsules	May-2024
18.	68462-391-30	17221177	30 capsules	May-2024
19.	68462-391-30	17221397	30 capsules	May-2024
20.	68462-390-30	17221395	30 capsules	May-2024
21.	68462-390-30	17221706	30 capsules	Jul-2024

Sr. no	NDC	Batch	Pack Size	Expiry Date
22.	68462-391-30	17221705	30 capsules	Jul-2024
23.	68462-390-30	17222028	30 capsules	Aug-2024
24.	68462-390-30	17222234	30 capsules	Sep-2024
25.	68462-391-30	17222011	30 capsules	Aug-2024
26.	68462-391-30	17222233	30 capsules	Sep-2024
27.	68462-390-30	17222517	30 capsules	Nov-2024
28.	68462-390-90	17222517	90 capsules	Nov-2024
29.	68462-391-30	17222516	30 capsules	Nov-2024
30.	68462-391-10	17222516	1000 capsules	Nov-2024
31.	68462-390-90	17230265	90 capsules	Dec-2024
32.	68462-390-30	17230265	30 capsules	Dec-2024
33.	68462-391-30	17230266	30 capsules	Dec-2024
34.	68462-391-10	17230266	1000 capsules	Dec-2024
35.	68462-390-10	17230437	1000 capsules	Jan-2025
36.	68462-390-30	17230437	30 capsules	Jan-2025
37.	68462-391-30	17230436	30 capsules	Jan-2025
38.	68462-390-30	17230572	30 capsules	Jan-2025
39.	68462-391-90	17230573	90 capsules	Jan-2025
40.	68462-391-30	17230573	30 capsules	Jan-2025
41.	68462-391-10	17230726	1000 capsules	Feb-2025
42.	68462-391-90	17230726	90 capsules	Feb-2025
43.	68462-391-30	17230726	30 capsules	Feb-2025
44.	68462-390-30	17230729	30 capsules	Feb-2025
45.	68462-390-90	17230729	90 capsules	Feb-2025
46.	68462-391-30	17230769	30 capsules	Nov-2024
47.	68462-390-10	17230776	1000 capsules	Nov-2024
48.	68462-390-90	17230776	90 capsules	Nov-2024
49.	68462-391-30	17230903	30 capsules	Mar-2025
50.	68462-391-90	17230963	90 capsules	Mar-2025
51.	68462-391-30	17230963	30 capsules	Mar-2025
52.	68462-390-30	17230919	30 capsules	Mar-2025
53.	68462-390-30	17230958	30 capsules	Mar-2025
54.	68462-390-90	17230958	90 capsules	Mar-2025
55.	68462-390-10	17230958	1000 capsules	Mar-2025
56.	68462-390-30	17231186	30 capsules	Apr-2025
57.	68462-391-30	17231190	30 capsules	Apr-2025



Market withdrawal of these batches have been initiated as an abundant precaution against the Out of Specification result for the test of organic impurities for the batch 17220002, reported at 18th month time point in the long term stability (commercial batch). However, no failure observed in any of above listed batches, which have been charged on stability. Recall for the batch, 17220002 was already initiated on October 18, 2023 and hence, not part of this market withdrawal.

See details of product batch listed in above table and refer enclosed product labels for ease in identifying the product. Glenmark Pharmaceuticals Inc. initiated shipment of this product (from these 57 batches) in Jan 25, 2022.

Examine your inventory and if you have any inventory available pertains to batch specified in above table then quarantine it immediately.

We are requesting the batch specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your market withdrawal Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your market withdrawal return please contact Inmar at 877-722-4329



Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan

Digitally signed by Thomas
Callaghan
Date: 2023.11.30 16:36:18 -05'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Market withdrawal Return Response Form



**MARKET WITHDRAWAL RETURN RESPONSE FORM
Esomeprazole Magnesium Delay Released Capsules USP 20 mg & 40 mg**

NDC for 20 mg: 30'S: 68462-390-30, 90'S: 68462-390-90 and 1000'S: 68462-390-10

NDC for 40 mg: 30'S: 68462-391-30, 90'S: 68462-391-90 and 1000'S: 68462-391-10

Wholesale Level

11/30/2023

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal instructions and have taken the appropriate action.

Customer Name:	DEA#:
<i>DEA # is required, if it is not provided, the processing of your form will be delayed.</i>	
Address:	
City:	State: Zip:
Contact Name (Please Print):	
Telephone#:	Email:
Contact Signature:	Date:
DEBIT MEMO# (If unsure, leave blank):	

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Ltd.:

Wholesaler Name:	DEA#:
City:	State: Zip:

I have checked my stock and communicated to my customers at the appropriate level:

I confirm that all locations that received the impacted products have been notified to the wholesale level _____ (Initial and date)

I do not have any stock of the market withdrawn items. **OR**

I have quarantined and listed in the box below the quantity of market withdrawn units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels _____.

Sr. no	NDC	Item Description	Lot#/Pack Size	Expiry Date	Total Full/sealed and partial /open bottle count
1	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17212405/ 30's pack Container	Nov-2023	
2	68462-390-90	Esomeprazole Magnesium Delay	17212405/	Nov-	

Sr. no	NDC	Item Description	Lot#/Pack Size	Expiry Date	Total Full/sealed and partial /open bottle count
		Released capsules USP 20 mg	90's pack Container	2023	
3	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17212406/ 30's pack Container	Nov- 2023	
4	68462-391-90	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17212406/ 90's pack Container	Nov- 2023	
5	68462-391-10	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17220001/ 1000's pack Container	Nov- 2023	
6	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17220001/ 30's pack Container	Nov- 2023	
7	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17220030/ 30's pack Container	Nov- 2023	
8	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17220031/ 30's pack Container	Nov- 2023	
9	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17220686/ 30's pack Container	Feb- 2024	
10	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17220685/ 30's pack Container	Feb- 2024	
11	68462-391-10	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17220685/ 1000's pack Container	Feb- 2024	
12	68462-391-90	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17220785/ 90's pack Container	Feb- 2024	
13	68462-390-10	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17220686/ 1000's pack Container	Feb- 2024	
14	68462-390-90	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17220784/ 90's pack Container	Feb- 2024	
15	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17220913/ 30's pack Container	Feb- 2024	
16	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17220912/ 30's pack Container	Feb- 2024	
17	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17221178/ 30's pack Container	May- 2024	
18	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17221177/ 30's pack Container	May- 2024	
19	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17221397/ 30's pack Container	May- 2024	
20	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17221395/ 30's pack Container	May- 2024	
21	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17221706/ 30's pack Container	Jul- 2024	
22	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17221705/ 30's pack Container	Jul- 2024	
23	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17222028/ 30's pack Container	Aug- 2024	

Sr. no	NDC	Item Description	Lot#/Pack Size	Expiry Date	Total Full/sealed and partial /open bottle count
24	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17222234/ 30's pack Container	Sep-2024	
25	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17222011/ 30's pack Container	Aug-2024	
26	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17222233/ 30's pack Container	Sep-2024	
27	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17222517/ 30's pack Container	Nov-2024	
28	68462-390-90	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17222517/ 90's pack Container	Nov-2024	
29	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17222516/ 30's pack Container	Nov-2024	
30	68462-391-10	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17222516/ 1000's pack Container	Nov-2024	
31	68462-390-90	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230265/ 90's pack Container	Dec-2024	
32	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230265/ 30's pack Container	Dec-2024	
33	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230266/ 30's pack Container	Dec-2024	
34	68462-391-10	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230266/ 1000's pack Container	Dec-2024	
35	68462-390-10	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230437/ 1000's pack Container	Jan-2025	
36	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230437 30's pack Container	Jan-2025	
37	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230436/ 30's pack Container	Jan-2025	
38	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230572 30's pack Container	Jan-2025	
39	68462-391-90	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230573/ 90's pack Container	Jan-2025	
40	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230573/ 30's pack Container	Jan-2025	
41	68462-391-10	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230726/ 1000's pack Container	Feb-2025	
42	68462-391-90	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230726/ 90's pack Container	Feb-2025	
43	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230726/ 30's pack Container	Feb-2025	
44	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230729/ 30's pack Container	Feb-2025	
45	68462-390-90	Esomeprazole Magnesium Delay	17230729/	Feb-	

Sr. no	NDC	Item Description	Lot#/Pack Size	Expiry Date	Total Full/sealed and partial /open bottle count
		Released capsules USP 20 mg	90's pack Container	2025	
46	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230769/ 30's pack Container	Nov- 2024	
47	68462-390-10	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230776/ 1000's pack Container	Nov- 2024	
48	68462-390-90	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230776/ 90's pack Container	Nov- 2024	
49	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230903/ 30's pack Container	Mar- 2025	
50	68462-391-90	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230963/ 90's pack Container	Mar- 2025	
51	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17230963/ 30's pack Container	Mar- 2025	
52	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230919/ 30's pack Container	Mar- 2025	
53	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230958/ 30's pack Container	Mar- 2025	
54	68462-390-90	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230958/ 90's pack Container	Mar- 2025	
55	68462-390-10	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17230958/ 1000's pack Container	Mar- 2025	
56	68462-390-30	Esomeprazole Magnesium Delay Released capsules USP 20 mg	17231186/ 30's pack Container	Apr- 2025	
57	68462-391-30	Esomeprazole Magnesium Delay Released capsules USP 40 mg	17231190/ 30's pack Container	Apr- 2025	

If you have any questions regarding this form or product return please contact Inmar at 877-722-4329
Office hours 9am to 5pm EST Mon thru Fri.

**Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com
Market Withdrawal Event ID RCL229-23 / N130993**


JAR SIZE : 60 CC
 LABEL SIZE : 105 mm x 45 mm

UNVARNISHED AREA FOR
 LOT NUMBER AND EXPIRY DATE
 32 mm x 45 mm

NOC 68462-390-30
Esomeprazole
Magnesium
Delayed-Release
Capsules, USP


20 mg*

PHARMACIST: Dispense the Medication Guide provided separately to each patient.


glenmark

Rx Only 30 Capsules

*Each delayed-release capsule contains Esomeprazole magnesium dihydrate equivalent to 20 mg esomeprazole.
Usual Adult Dosage: See package insert.
 Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
 Keep container tightly closed.
Medication Guide available at www.glenmarkpharma-us.com/medguides
 Manufactured for Glenmark Pharmaceuticals Inc., USA
 17730
 Producers of India
 MFCRUS2592010
 1221



3 68462 39030 46
 Question? 1 (866) 721-7115
 www.glenmarkpharma-us.com

MINIMUM FONT SIZE: 4 pt

DATE: 09-12-2021
 VERSION: 05

<p>G GLENMARK PHARMACEUTICALS LTD.</p> <p>PRODUCT NAME: Esomeprazole Mag DR Cap 20mg</p> <p>ITEM CODE: PE60091 VERSION: 1221-1</p> <p>PHARMACODE: NA</p> <p>COUNTRY: USA</p> <p>LOCATION: Indore</p> <p>PACK : Label 30's</p> <p>ACTUAL SIZE: 105 mm x 45 mm</p> <p>SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED</p>	DATE:	PANTONE SHADE NO: 186 C 364 C Non printing colour	
	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
	RA	Regulatory Text	
	PRODUCTION:	Machine Suitability	
	QA:	Entire Text	
	REMARKS:		
	FCPDC001/01.00		

JAR SIZE : 100 CC
 LABEL SIZE : 105 mm x 45 mm

UNVARNISHED AREA FOR
 LOT NUMBER AND EXPIRY DATE
 32 mm x 45 mm

NDC 68462-390-90

**Esomeprazole
 Magnesium
 Delayed-Release
 Capsules, USP**

20 mg*

PHARMACIST: Dispense the Medication Guide
 provided separately to each patient.


 Glenmark

Rx Only 90 Capsules


*Can also be taken orally as tablets. Esomeprazole
 magnesium delayed-release capsules are 20 mg esomeprazole
 magnesium delayed-release capsules. See package insert.
 Usual Adult Dosage: See package insert.
 Store at 20°C to 25°C (68°F to 77°F); excursions permitted to
 15°C to 30°C (59°F to 86°F) [see USP Controlled Room
 Temperature].
 Keep container tightly closed.
 Medication Guide available at
 www.glenmark.com/esomeprazole
 Manufactured for: Glenmark
 Pharmaceuticals, Inc., USA
 Mahwah, NJ 07430
 Product of India
 MFD/RUS/26/02010
 1221

04808071 (888) 721-7115
 www.glenmark-usa.com

PE600921221-1

MINIMUM FONT SIZE: 4 pt

DATE: 09-12-2021
 VERSION: 04

<p> GLENMARK PHARMACEUTICALS LTD.</p> <p>PRODUCT NAME: Esomeprazole Mag DR Cap 20mg</p> <p>ITEM CODE: PE60092 VERSION: 1221-1</p> <p>PHARMACODE: NA</p> <p>COUNTRY: USA</p> <p>LOCATION: Indore</p> <p>PACK : Label 90's</p> <p>ACTUAL SIZE: 105 mm x 45 mm</p> <p>SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED</p>	DATE:	PANTONE SHADE NO: 186 C 364 C BLACK Non printing colour	
	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
	RA	Regulatory Text	
	PRODUCTION:	Machine Suitability	
	QA:	Entire Text	
	REMARKS:		
	FCPDC001/01.00		

JAR SIZE : 625 CC
 LABEL SIZE : 180 mm x 80 mm

UNVARNISHED AREA FOR
 LOT NUMBER AND EXPIRY DATE
 32 mm x 80 mm

NDC 68462-390-10
**Esomeprazole
 Magnesium
 Delayed-Release
 Capsules, USP**

20 mg*

PHARMACIST: Dispense the Medication Guide
 provided separately to each patient.



Rx Only

1000 Capsules

*Each delayed-release capsule contains Esomeprazole
 magnesium dihydrate equivalent to 20 mg esomeprazole.

Usual Adult Dosage: See package insert.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to
 15°C to 30°C (59°F to 86°F) [see USP Controlled Room
 Temperature].

Keep container tightly closed.

Medication Guide available at

www.glenmarkpharma-us.com/medguides

Manufactured for:
 Glenmark Pharmaceuticals Inc., USA
 Mahwah, NJ 07430

Product of India

MP/DRUGS/25/9/2010
 12/21



Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

PE600931221-1

MINIMUM FONT SIZE: 7.5 pt

DATE: 09-12-2021
 VERSION: 04

GLENMARK PHARMACEUTICALS LTD. PRODUCT NAME: Esomeprazole Mag DR Cap 20mg ITEM CODE: PE60093 VERSION: 1221-1 PHARMACODE: NA COUNTRY: USA LOCATION: Indore PACK : Label 1000's ACTUAL SIZE: 180 mm x 80 mm SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED	DATE:	PANTONE SHADE NO: 186 C 364 C BLACK Non printing colour	
	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
	RA	Regulatory Text	
	PRODUCTION:	Machine Suitability	
	QA:	Entire Text	
	REMARKS:		
	FCPDC001/01.00		

JAR SIZE : 75 CC
 LABEL SIZE : 105 mm x 45 mm

UNVARNISHED AREA FOR
 LOT NUMBER AND EXPIRY DATE
 32 mm x 45 mm

NDC 68462-391-30
Esomeprazole
Magnesium
Delayed-Release
Capsules, USP

40 mg*

PHARMACIST: Dispose the Medication Guide provided separately to each patient.

G
 glenmark

Rx Only 30 Capsules

*Each delayed-release capsule contains Esomeprazole Magnesium Delayed-Release Capsules, USP, 40 mg (esomeprazole).
 Usual Adult Dosage: See package insert.
 Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
 Keep container tightly closed.
 Medication Guide available at www.glenmarkpharma-us.com/medguides
 Esomeprazole Magnesium Delayed-Release Capsules, USP
 Glenmark Pharmaceuticals Inc., USA
 Mahwah, NJ 07430
 Product of India
 MFD/RLS/25/6/2010
 1221



PE600941221-1
 04/12/15
 www.glenmarkpharma-us.com

MINIMUM FONT SIZE: 4 pt

DATE: 09-12-2021
 VERSION: 04

GLENMARK PHARMACEUTICALS LTD. PRODUCT NAME: Esomeprazole Mag DR Cap 40mg ITEM CODE: PE60094 VERSION: 1221-1 PHARMACODE: NA COUNTRY: USA LOCATION: Indore PACK : Label 30's ACTUAL SIZE: 105 mm x 45 mm SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED	DATE:	PANTONE SHADE NO: <input type="checkbox"/> 185 C <input type="checkbox"/> 60% OF BLACK <input type="checkbox"/> BLACK <input type="checkbox"/> Non printing colour		
	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout		
	RA	Regulatory Text		
	PRODUCTION:	Machine Suitability		
	QA:	Entire Text		
	REMARKS:			
	FCPDC001/01.00			

JAR SIZE : 120 CC
 LABEL SIZE : 105 mm x 45 mm

UNVARNISHED AREA FOR
 LOT NUMBER AND EXPIRY DATE
 32 mm x 45 mm

NDC 66462-391-90
**Esomeprazole
 Magnesium
 Delayed-Release
 Capsules, USP**

40 mg[±]

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Glenmark

Rx Only 90 Capsules

*Each delayed-release capsule contains Esomeprazole Magnesium Delayed-Release Capsules, USP 40 mg (esomeprazole magnesium) and Magnesium Oxide. See package insert for full prescribing information. Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Keep container tightly closed. Excursions shall not exceed the limits defined in the USP Controlled Room Temperature range. See www.glenmarkpharm-usa.com/medguide for more information. © Glenmark Pharmaceuticals, Inc., USA, Mahwah, NJ 07430 MF7DR0525A/2010 1221

6646239190117

Questions? 1 (800) 731-7115
 www.glenmarkpharm-usa.com

FE60091221-1

MINIMUM FONT SIZE: 4 pt

DATE: 09-12-2021
 VERSION: 04

GLENMARK PHARMACEUTICALS LTD.	DATE:	PANTONE SHADE NO: <input type="checkbox"/> 186 C <input type="checkbox"/> 80% OF BLACK	
		<input type="checkbox"/> BLACK <input type="checkbox"/> Non printing colour	
PRODUCT NAME: Esomeprazole Mag DR Cap 40mg	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: PE60095 VERSION: 1221-1	RA:	Regulatory Text	
PHARMACODE: NA	PRODUCTION:	Machine Suitability	
COUNTRY: USA	QA:	Entire Text	
LOCATION: Indore	REMARKS:		
PACK : Label 90's			
ACTUAL SIZE: 105 mm x 45 mm			
SPECIFICATION:	A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED		
	FCPDC001/01.00		

JAR SIZE : 750 CC
 LABEL SIZE : 130 mm x 70 mm

UNVARNISHED AREA FOR
 LOT NUMBER AND EXPIRY DATE
 32 mm x 70 mm

NDC 68462-391-10

**Esomeprazole
 Magnesium
 Delayed-Release
 Capsules, USP**

40 mg*

PHARMACIST: Dispense the
 Medication Guide provided
 separately to each patient.


glenmark

Rx Only 1000 Capsules




*Each delayed-release capsule contains Esomeprazole
 magnesium dihydrate equivalent to 40 mg esomeprazole.
Usual Adult Dosage: See package insert.
 Store at 20°C to 25°C (68°F to 77°F); excursions permitted to
 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
 Keep container tightly closed.

Medication Guide available at
www.glenmarkpharma-us.com/medguides
 Manufactured for: Glenmark
 Pharmaceuticals Inc., USA
 Mahwah, NJ 07430
 Product of India
 MP/DRUGS25/9/2010
 12/21
 PE600961221-1

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

MINIMUM FONT SIZE: 6.5 pt

DATE: 09-12-2021
 VERSION:05

 GLENMARK PHARMACEUTICALS LTD.		DATE:	PANTONE SHADE NO:  186 C  60% OF BLACK
PRODUCT NAME: Esomeprazole Mag DR Cap 40mg		PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE: PE60096 VERSION: 1221-1		RA	Regulatory Text
PHARMACODE: NA		PRODUCTION:	Machine Suitability
COUNTRY: USA		QA:	Entire Text
LOCATION: Indore		REMARKS:	
PACK : Label 1000's			
ACTUAL SIZE: 130 mm x 70 mm			
SPECIFICATION:	A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED		
	FCPDC001/01.00		

INDICATIONS FOR PROPRANOLOL HYDROCHLORIDE

Propranolol hydrochloride is indicated for the treatment of hypertension, angina pectoris, myocardial infarction, and certain types of arrhythmias. It is also indicated for the treatment of migraine, essential tremor, and hyperthyroidism.

CONTRAINDICATIONS

Propranolol hydrochloride is contraindicated in patients with asthma, chronic obstructive pulmonary disease, second-degree or third-degree atrioventricular block, and severe peripheral vascular disease.

WARNINGS

Propranolol hydrochloride may mask the hypotensive effect of other antihypertensive agents. It may also mask the signs and symptoms of hypoglycemia and hypothyroidism.

ADVERSE REACTIONS

Common adverse reactions include dizziness, fatigue, and bradycardia. More serious reactions include bronchospasm, heart block, and hypotension.

DRUG INTERACTIONS

Propranolol hydrochloride interacts with other antihypertensive agents, antiarrhythmic drugs, and thyroid medications.

HOW SUPPLIED

Propranolol hydrochloride is available in 10 mg and 20 mg tablets. It is also available as an oral solution.

HOW TO USE

Propranolol hydrochloride should be taken orally, with or without food, as directed. The usual adult dose is 160 mg per day.

HOW TO STORE

Propranolol hydrochloride tablets should be stored at room temperature (20° to 25°C). The oral solution should be stored at room temperature.

HOW TO HANDLE

Propranolol hydrochloride is a Schedule II controlled substance. It should be handled in accordance with applicable laws and regulations.

HOW TO PACKAGE

Propranolol hydrochloride is available in 10 mg and 20 mg tablets. It is also available as an oral solution.

HOW TO DISPENSE

Propranolol hydrochloride should be dispensed in accordance with applicable laws and regulations.

HOW TO LABEL

Propranolol hydrochloride should be labeled in accordance with applicable laws and regulations.

HOW TO MARK

Propranolol hydrochloride tablets should be marked in accordance with applicable laws and regulations.

HOW TO IDENTIFY

Propranolol hydrochloride should be identified in accordance with applicable laws and regulations.

HOW TO TEST

Propranolol hydrochloride should be tested in accordance with applicable laws and regulations.

HOW TO ANALYZE

Propranolol hydrochloride should be analyzed in accordance with applicable laws and regulations.

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Maximum Dose of 20 mg once daily is recommended for patients with severe liver impairment (Child-Pugh Class C)

Contraindications include asthma, chronic obstructive pulmonary disease, second-degree or third-degree atrioventricular block, and severe peripheral vascular disease.

Warnings

Propranolol hydrochloride may mask the hypotensive effect of other antihypertensive agents. It may also mask the signs and symptoms of hypoglycemia and hypothyroidism.

Adverse Reactions

Common adverse reactions include dizziness, fatigue, and bradycardia. More serious reactions include bronchospasm, heart block, and hypotension.

Drug Interactions

Propranolol hydrochloride interacts with other antihypertensive agents, antiarrhythmic drugs, and thyroid medications.

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How to Analyze

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Product information form for Propranolol Hydrochloride, including fields for Product Name, NDC, Manufacturer, and other details.

Product information form for Propranolol Hydrochloride, including fields for Description, Dosage, and other details.

