



# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 Introduction Type:  Post Launch Change  Final Version Date: 6/23/2024

## PRODUCT INFORMATION

Company Name: Camber Pharmaceuticals Application: ANDA

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 211977

Medical Device Class, if applicable:

DUNS: 11-856-3719

Proprietary Name (If Applicable) and Established Name: Esomeprazole Magnesium Delayed-Release Capsules, USP 40 mg

Selling Unit NDC: 31722-665-30 Unit of Use NDC: 31722-665-30 UPC: 331722665308

CVX Code: MVX Code:

Description: Esomeprazole Magnesium Delayed-Release Capsules, USP 40 mg

Active Ingredient(s): Esomeprazole magnesium trihydrate, USP

URL for Additional Product Information: [www.camberpharma.com](http://www.camberpharma.com)

Address: 800 Centennial Ave, Suite 1 Address 2:

City: Piscataway State: NJ Zip: 08854

Key Contact: Customer Service Email: [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)

Phone Number: 1-866-827-3647 Fax: 732-562-8788

Product Therapeutic Classification: Proton pump inhibitor (PPI)

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

a. Temperature - Indicate the USP temperature range for this product.

Temperature Range:  Controlled Room - between 20 and 25 C (68° - 77° F)

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice?  No

Is this product to be shipped to customers on dry ice?  No

b. Contact for temperature excursion questions:

Name: Soma Raju

Number: 732-529-0423

Group E-mail: [somaraju@heterousa.com](mailto:somaraju@heterousa.com)

c. Special regulations for product in any states?

Special returns requirements for this product?  No

d. Store product (unit of sale) upright?  No

Protect product (unit of sale) from light?  No

e. Shelf life:

Initial shelf life at launch (if different):  24 Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?  No

if yes, enter class #

a product kit?  No

if yes, list NDCs of component parts reverse numbered?

co-licensed?  No

latex-free?  Yes

preservative-free?  Yes

correctional institution block?  No

opioid?  No

Cannabinoid?  No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

Is the Product... Direct-Ship Only

Is the Product... Unit of Use

Orphan Drug Status

FDA Approval Status

Allergens Present: Alcohol, Animal Products, Sugar

Country of Origin: India

Is this product covered under the Trade Agreements Act (TAA)?  No

## PRODUCT DESCRIPTION INFORMATION

Size: 30 ct

Strength: 40 mg

Dosage Form: Hard gelatin, delayed-release capsule

Product Shape: Capsule

Product Color: White opaque cap and white opaque body

Product Imprint: Imprinted with 'H' on cap and 'E3' on body

## ORDER INFORMATION

Unit of Sale:  Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Powder Multi

Other: Write In

What is the NDC selling unit?  1 Bottle of 30 Capsules

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?  Yes

If Yes, how many of which package type?

24 Each

Inner/ Carton/ Pack

Case

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:  AB  Authorized Generic \*If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?: Nexium

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

Each

Gram

Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  Yes  No

Is product exempt from DSCSA?  No

If yes, select exemption: Other exemption - Write in:

Is product repackaged?  No

Is product sold by manufacturer's exclusive distributor?  Yes

Has FDA granted waiver/exception/exemption for product?  No

If yes, attach documentation from FDA.

GLN: 0331722498975

GCP:

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.07	1.5	1.5	2.75	6.19	1
Box/Carton/Bundle/Inner Pack:						
Case:	2.25	9.75	7	4	273.00	24
Pallet:						

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722665308	00331722665308
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722665302	
<input type="checkbox"/> Pallet				

## COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$) \$10.00

As of date: 8/13/2021

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

\*Please provide any additional information on page 2. Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. See new p. 3 for Designated Drop Ship Only. Signature:



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Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																																																													
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No            Is the product a Esomeprazole Magnesium Delayed Release Capsules 40mg <input type="checkbox"/> No            Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this Esomeprazole Magnesium Delayed Release Capsules 40mg Oral Solid, Cap (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No            RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity  <input type="checkbox"/> Consumer Commodity, ORM-D  <input type="checkbox"/> Small Quantity (49 CFR 173.4)  <input type="checkbox"/> Special Permit; DOT-SP  <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);            SP# <input type="text"/></p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #003366; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">SDS Hazard Classification</th> </tr> </thead> <tbody> <tr> <td style="width: 50%; padding: 2px;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; padding: 2px;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Inorganic</td> <td style="padding: 2px;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Steroid/Androgen</td> <td style="padding: 2px;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Does the product have an Aerosol class? 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