

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	6/23	
			PRODUCT INFORMA	ATION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Camber Pharmaceuticals Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN			ce):	2119	977				Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applica			·						, ,					
DUNS:	11-856-3719							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Esom	eprazole Magnesium Delaye	ed-Release Capsu	ıles, USP 20 m	g		I	(write in)	•				
Selling Unit NDC:	31722-664-30		Unit of Use NDC:		31722-664-30		722664301		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Esomeorazole Ma	gnesium Delaved-R	elease Capsules, USP 20 m	ıa				T	Is this product to be shippe	d to customers on ic	e?		No	1
		g,,		9					Is this product to be shippe				No	
Active Ingredient(s):		Esomeprazole mag	gnesium trihydrate, USP								•			
							b. Contact fo	r temperature excursion qu	estions:					
URL for Additional Product Inform	mation:	www.camberpharm	na.com						Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:	NJ Zip	: 08854		Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service				Email:	customerservice@cam	berpharma.com							1
Phone Number:	1-866-827-3647	la			Fax:	732-562-8788		c. Special reg	gulations for product in any				No	
Product Therapeutic Classification	on:	Proton pump inhibi	itor (PPI)						Special returns requirement	is for this product?			No	
	A DDITI	NAL PROPUST IN	IFORMATION.			PROBLICT DESC	DIDTION INFORMATION							1
	ADDITIO	DNAL PRODUCT IN	NFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly				Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						Initial shelf life at launch (if different):				Months
a product kit?		No	ED 4 4 101-1			Strength:	20 mg			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				Hard gelatin, delayed-			ORDER INFORM	ATION			
component parts reverse numbered?		No				Dosage Form:	release capsule		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present				release capsule		x Bottle		1 Bottle of 30		unit.	
latex-free?		Yes					Capsule		Box/Carton		(Write-in, e.		0 Vials)	
preservative-free?		Yes	Alcohol, Anima	al Products, Suga	ar	Product Shape:			Ampule			,	,	
correctional institution block?		No				Product Color:	White opaque cap and		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:	white opaque body		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Imprinted with 'H' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					r roduct imprint.	and 'E2' on body		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?														
			Is this product covered to						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Is this product covered to Trade Agreements Act (No				Vial Powder Multi			Inner/Carton	/Pack	
			Trade Agreements Act (TAA)?	No								/Pack	
				TAA)?	No				Vial Powder Multi			Inner/Carton	/Pack	
			Trade Agreements Act (TAA)?					Vial Powder Multi Other: Write In	MANAY ODDER		Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?			uthorized Generic, other		Vial Powder Multi Other: Write In	IARMACY ORDER	/ BILL UNIT	Inner/Carton Case		
If Unit Dose, indicate NDC here:	AB		Trade Agreements Act (TAA)?			uthorized Generic, other on fields are not applicable	Rec. sell unit	Vial Powder Multi Other: Write In	IARMACY ORDER		Inner/Carton Case		
If Unit Dose, indicate NDC here:		Nexium	Trade Agreements Act (TAA)?					Vial Powder Multi Other: Write In PH to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Cartor Case nit to pharma		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)?	Aut			Rec. sell unit	Vial Powder Multi Other: Write In PH to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Cartor Case hit to pharma Each Gram		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)?	Aut				Vial Powder Multi Other: Write In PH to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Cartor Case nit to pharma		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT	(TAA)?	Aut	sect			Vial Powder Multi Other: Write In Place to customer?		/ BILL UNIT Rx billing u	Inner/Cartor Case hit to pharm Each Gram Milliliter		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	DRUG SUPP	Trade Agreements Act ((TAA)?	Aut				Vial Powder Multi Other: Write In Place to customer?	IARMACY ORDER	/ BILL UNIT Rx billing u	Inner/Cartor Case hit to pharm Each Gram Milliliter		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA?	and?:	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	(DSCSA) INFORM	Aut	sect			Vial Powder Multi Other: Write In Place to customer?	I AND PACKING IN	/ BILL UNIT Rx billing us	Inner/Cartor Case nit to pharm. Each Gram Milliliter	acy:	Salashia "
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption:	and?:	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	(DSCSA) INFORM	Aut	sect			Vial Powder Multi Other: Write In Place to customer?	I AND PACKING IN Dimensio	/ BILL UNIT Rx billing un IFORMATION Ons (US msm	Inner/Cartor Case nit to pharm Each Gram Milliliter	acy:	Saleable #
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No	(DSCSA) INFORM	Auti MATION GLN: GCP:	0331722498975	ion fields are not applicable	(Write-in, e.g	Vial Powder Multi Other: Write In PH to customer? 1 Vial) ITEL Weight Lbs.	I AND PACKING IN Dimensie Depth	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width	Inner/Cartor Case iit to pharm Each Gram Milliliter its.) Height	Volume (Cube)	Pieces
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	X Organic Corrosive						
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No							
Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	Inorganic Oxidizer Steroid/Androgen Contact Hazard						
boes the product laber bear a OAT top 65 warming:	otelou/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug? No						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number							
b. Proper Shipping Name	0 1 10 10 10 10						
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number	1						
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
e. Inhalation Hazard?							
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No RQ Threshold:	REMS: No REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4) Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Connents						
SP#	Registry: No						
• • •	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No							
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes							
Restricted to retail pharmacy only:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:	product in certain states?						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						



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

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?