

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

Version 2024						Introduction Type:	New Item		x Final Version			Date:	7/24	/2024
			PRODUCT INFORMAT	ION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals. Inc.				Application:	ANDA	a. Temperature -	- Indicate the USP tempe	erature range for th	nis product.			
Application Number for NDA/ANI)			NDA 505(b) Type:	NOT APPLICABLE		emperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:								•					
DUNS:	11-856-3719							ot ot	ther Temperature Range I	Requirement				
Proprietary Name (If Applicable) a		ame: Ezetimi	ibe Tablets, USP 10 mg						(write in)					
Selling Unit NDC:	31722-628-90		Unit of Use NDC:		31722-628-90		722628907	No.	otes					
UDI			CVX Code:			MVX Code:								
Description:	Ezetimibe Tablet	s, USP 10 mg						ls ls	this product to be shipped	d to customers on ic	e?		No	
								ls ls	this product to be shipped	d to customers on d	ry ice?		No	
Active Ingredient(s):		Ezetimibe, USP												
URL for Additional Product Inform		www,camberpharma							mperature excursion qu	estions:	Soma Raju			
Address:	800 Centennial A		<u>,com</u>			Address 2:			ame: umber:		732-529-042	2		
City:	Piscataway	State:					: 08854		roup E-mail:			neterousa.cor	n	
Key Contact:	Customer Service	e		berpharma.com	1					_				
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regula	tions for product in any	states?			No	
Product Therapeutic Classification	n:	Selective cholestero	l absorption inhibitor					s _r	pecial returns requirement	ts for this product?			No	
														_
	ADD I T	IONAL PRODUCT INF	FORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			s the Product	Direct-Ship Or	ıly			Pr	rotect product (unit of sa	ale) from light?			No	
a legend device?		No	s the Product	Unit of Use		Size:	90 ct	e, Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			OIZC.		lni	itia l she l f life at launch (if different):				Months
a product kit?	No Strength: 10 mg									ODDED INCODE	ATION			
if yes, list NDCs of			FDA Approval Status			_	Tablet			ORDER INFORM	IATION			
component parts reverse numbered?		No				Dosage Form:	rablet	11.	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 9		u	
latex-free?		Yes				B	Capsule, flat faced, bevel		Box/Carton			g. 1 Box of 10	0 Via l s)	
preservative-free?		Yes	Dairy, Lactose, Cas	sein, wney, Alco	onoi	Product Shape:	edged		Ampu l e		,	•	,	
correctional institution block?		No				Product Color:	White to off-white		Glass		Minimum o	rder quantity	?	Yes
opioid?		No				i rouder dejer.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'I' on one side and '83' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u hospital scanning?	init dose for		In this was done			•	and oo on the other side		Vial Liquid Multi Vial Powder Sgl		If Yes, how		ch package	type?
If Unit Dose, indicate NDC here:			Is this product covered un Trade Agreements Act (T.		No				Vial Powder Sgi Vial Powder Multi		24	Each Inner/Carton	/Pack	
If Offic Bose, indicate NBO fiere.				, , , ,	140				Other: Write In			Case	n ack	
			FOR GENERIC DRUG PRO	DDUCTS								1		
								7						
					Au	thorized Generic *If A	uthorized Generic, other		P⊦	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sect	ion fields are not applicable	Rec. sell unit to	customer?		Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bra	nd?:	Zetia										Each		
								(Write-in, e.g. 1 \	/ial)			Gram		
		DRUG SUPPLY	Y CHA I N SECUR I TY ACT (E	DSCSA) INFOR	MATION			HCPCS J-Code:				Milliliter		
Does supplier meet DSCSA definit	tion of manufactu	ror?	Yes	٦.	GLN:	0331722498975			ITEN	M AND PACKING IN	JEORMATIO	M		
Is product exempt from DSCSA?	lion of manufactu	liel :	No 103	-	GLIN.	0001722490970			1151	AND I ACIDING III	II OKMATIO	`		
If yes, select exemption:					GCP:					Dimonei	ons (US msn	ate \	Volume	Saleable #
Other exemption - Write in:					GCP:				Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	I	f ves. was or	iginal product purchase	d	Item/Each:		1				
Is product sold by manufacturer's	exclusive distrib	utor?	Yes		direct from m				0.08	1.5	1.5	2.55	5.74	1
Has FDA granted waiver/exception			No		Provide sour	ce manufacturer for repa	ackaged product	Box/Carton/Bund	dle/					
If yes, attach documentation fror	m FDA.							Inner Pack:						
		0.71						Case:	2.9	11.25	8	4.5	405	24
		GIII	N AND H I BCC PRODUCT I N	IFORMATION				D. II.						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		CTI	N-14	Unit of Use GTIN-14	Pallet:						
Saleable Clin of Micasule	iti ib tag(1/N)	Quantity	THEOU		311	14 17	O.I.I. 01 036 G1114-14							
x Item/Each	N	1			003	31722628907	00331722628907							
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESALI	ER USE ONL	_Y:
X Case	N	24			203	31722628901								
Pallet								Regular Cost			Vendor #:	_		
								Invoice Cost (WA	AC) (\$)	\$18.90	Whsl. Code			
								As of date:	5/30/2023		Fineline Co	ae:		
								As of date.	3/30/2023		I			
			Attach copy of SAFETY DA	TA SHEET (SDS	S) or non haza	rd letter, PACKAGE INSE	RT, LABEL AND PHOTO OF P	PRODUCT PACKAGII	NG and BARCODE.					



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Version 2024 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No x Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Contact Hazard No Steroid/Androgen c. Contact Hazard? Does the product have an Aerosol class? If yes, No Nο identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? Nο Is this product regulated for shipment by DOT? No 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 c. DOT Hazard Class Hazardous Waste Identification d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number 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? Med Guide Required Is the product restricted for air shipment? If so, indicate restriction: No Passenger Limited Distribution Requirement Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: No RQ Threshold: REMS Program Manager Name: Phone: Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Wholesale distributor support: Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Provider Name: DEA #: Limited Quantity Site Enrollment Number assigned NCPDP# Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION

Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No 1-866-827-3647 ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged Schedule No. Is it a scheduled listed chemical product?: No Yes 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 contact - customerservice@camberpharma.com Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No No Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Nο Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier						
a. EDI	Cut off time:						
b. Autofax Fax Number:							
c. Fax Fax Number:	Shipping lead time of PO: Hours Days						
d. Phone only Phone No.:							
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:						
Minimum Order Quantity: Supplier's Customer Service Number:	Ships for second day receipt: Ships regular ground for 3-10 days receipt:						
Contracted 3PL company / contact #: Name:	Ships regular ground for 3-10 days receipt.						
Phone:							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:	Overnight receipt available:						
Drop Ship service fee billed with each order:	PO Receipt cut off time:						
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday						
Comments:	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, clinics and physician offices Restricted to retail pharmacy only:	Saturday Overnight receipt available:						
Restricted to hospital, clinics, and physician offices only:	PO Receipt Cut off time: Phone: Phone #:						
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax#:						
Comments:	EDI:						
	Overnight Fees apply:						
	Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:							
Physician Name:							
i nysician Name.	Contact # if product is received damaged: Is product returnable for credit:						
Physician/Clinic Phone #	Contact # if product is received damaged:						
Physician/Clinic Phone # Physician State License #	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy:						
Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #:	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?						
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:						
Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #:	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?						
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?						
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?						
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?						
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?						