

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

Version 2024						Introduction Type	e: New Item		x Final Version			Date:	8/1/2	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 temp	erature range for th	nis product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	O(k): 209403				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:								· -					
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Cinacalo	cet Tablets 90 mg						(write in)					
Selling Unit NDC:	31722-105-30		Unit of Use NDC:		31722-105-30		1722105309		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Cinacalcet Tablet	ts 90 mg						l:	s this product to be shippe	d to customers on ic	ce?		No	
								ŀ	s this product to be shipped	d to customers on d	ry ice?		No	
Active Ingredient(s):		Cinacalcet hydrochlor	ride							_				
UBL for Additional Brade destination									emperature excursion qu	estions:	Soma Raju			
URL for Additional Product Inform Address:	800 Centennial A	www.camberpharma.	com		1	Address 2:			Name: Number:		732-529-042	2		
City:	Piscataway	ive, Juile 1			State:		ip: 08854		Group E-mail:			eterousa.con	<u> </u>	
Key Contact:	Customer Service	e			Email:	customerservice@ca		· ·	Sroup E mail.		<u>oomaraja or</u>	0.010000.001	<u>.</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u> </u>	c. Special regul	lations for product in any	states?			No	
Product Therapeutic Classification	n:	Calcium sensing rece	eptor agonist (calcimimetic)		1			5	Special returns requirement	ts for this product?			No	
•					1									_
	ADDITI	IONAL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	nly			F	Protect product (unit of sa	ale) from light?			No	ī
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			Size:		1	nitial shelf life at launch (if different):				Months
a product kit?		No				Strength:	90 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts		NI-				Dosage Form:	Film coated tablet		Jnit of Sale		What is the	NDC selling	unit?	
reverse numbered? co-licensed?		No No	Allergens Present						x Bottle		1 Bottle of 3		unitr	
latex-free?		Yes					Oval, biconvex		Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?		Yes	Dairy, Lactose, Casein	, Whey, Corn,	Alcohol	Product Shape:	Svai, Bissiivex		Ampule		(**************************************	g. 1 Box 01 11	, viaio,	
correctional institution block?		No				Product Color:	Light green		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	Debossed with 'H' on one side and 'C8' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for						Go di ale dilei dide		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered un Trade Agreements Act (Tr		No				Vial Powder Sgl Vial Powder Multi			Each	/DI-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (17	AA)?	NO			-	Other: Write In			Inner/Carton Case	Раск	
			FOR GENERIC DRUG PRO	DUCTE				_	Other. Write in			Case		
			FOR GENERIC DRUG FRO	DUCIS										
					Au	thorized Generic *If	Authorized Generic, other		Pŀ	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			П			ction fields are not applicable	Rec. sell unit to				nit to pharma	.01	
II. Generic Equivalent to What Brai		Sensipar						reco. Sen unit te	Customeri		IXX Dilling ti	Each	icy.	
Conone Equivalent to Timat Brai								(Write-in, e.g. 1	Vial)	_		Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFOR	RMATION			HCPCS J-Code	: '			Milliliter		
Does supplier meet DSCSA definit	tion of manufactu	irer?	Yes	_	GLN:	0331722498975			ITEN	AND PACKING IN	NFORMATION	1		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm	•	Volume	Saleable #
Other exemption - Write in:									110.9.11 2.001	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	and the last of the table		No Yes	-	If yes, was or direct from m	riginal product purcha	sed	Item/Each:	0.12	1.5	1.5	3	6.75	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	+		iir ? ce manufacturer for re	nackaged product	Box/Carton/Bu	adla/					-
If yes, attach documentation from		TOUUCE?	110	7	Frovide Sour	ce manufacturer for re	packageu product	Inner Pack:	nule/					
. , ,								Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION					2.85	9.5	6.5	4	247	24
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTIN-14							
		Quantity												
x Item/Each	N	1			003	31722105309	00331722105309		COST INFORMATION			WHOLESALE	D HEE ON	V.
Box/Carton/Bundle/Inner Pack X Case	N	24			303	31722105300			COST INFORMATION			MHOLESALI	IN USE UNL	-1
Pallet	IV	2-7			303	322100000		Regular Cost			Vendor #:			
								Invoice Cost (W	/AC) (\$)	\$65.00	Whsl. Code	#:		
								1		44	Fineline Co			
								As of date:	3/1/2023]			
								1			1			
					_			1						
*Please provide any additional info			Attach copy of SAFETY DAT	TA SHEET (SD	S) or non haza		SERT, LABEL AND PHOTO OF P		SING and BARCODE.					



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

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/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?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	ii yes, indicate which.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
, ,	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMOUT REGISTRY RESTRICTIONS						
	Is there a REMS on this product?						
b. Proper Shipping Name c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
e. Inhalation Hazard?	Website UKL.						
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	REMS: No						
RQ Threshold:	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)	Comments						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ADDII CTODAGE INFORMATION	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	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	INU						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANEO	DUS NOTES and/or Image of Product Barcode:						



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

Version 2024

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: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday					
	Priority Overnight receipt available:					
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	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?					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure? Is product order for restocking purposes?					