

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

Version 2021						Introduction Ty	ype:	New Item		000 Final Version			Date:	5/19	/2023
			PRODUCT INFORMA	TION						SPECIAL HA	NDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Application	Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216229						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicable:															
DUNS:	11-856-3719									Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Defera	sirox Oral Granules 90mg							(write in)	•				
Selling Unit NDC:	31722-029-32		Unit of Use NDC:			UPC:	3317220	029322		Notes					
UDI			CVX Code:			MVX Code:									
Description:	Deferasirox Oral 0	Granules 90mg								Is this product to be shipp	ed to customers on i	ce?		No	1
										Is this product to be shipp				No	
Active Ingredient(s):		Deferasirox										•			-
									b. Contact for	r temperature excursion of	uestions:				
URL for Additional Product Inform		www.camberpharma								Name:		Soma Raju			
Address:		Ave (and) 800 Center	nial Ave, Suite 1			Address 2:				Number:		732-529-042			
				Zip:		Group E-mail: somaraju@heterousa.com									
Key Contact:				customerservice@camberpharma.com			4				1				
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special reg	julations for product in an	-			No	-
Product Therapeutic Classification	1:	Iron-Chelating Ager	nt							Special returns requireme	nts for this product?			No	
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?															
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT DE	ESCRIP	TION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly					Protect product (unit of	sale) from light?			No	
a legend device?		No	Is the Product	Unit Dose		Size:	3	80ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status							Initial shelf life at launch	(if different):				Months
a product kit?		No				Strength:	9	90mg			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status			_		2.10101			ORDER INFORM	IATION			
component parts reverse numbered?		INI.				Dosage Form:		Oral Granules - Granular bowder in child-reisistant		Unit of Sale		What is the	NDC colling	unit?	
co-licensed?		No No	Allergens Present				Р	oowaci iii ciiiia icisistant		Bottle		1 carton of 3		unitr	
latex-free?		Yes	Allergens riesent				N	V/A		x Box/Carton		(Write-in, e.		(slei)	
preservative-free?		Yes				Product Shape	e:	***		Ampule		(**************************************	g Dox o	o viaio,	
correctional institution block?		No					w	white to off white granular		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color		oowder		Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri	N	V/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					Product Imprii	int:			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?		No	Is this product covered u							Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:		31722-029-31	Trade Agreements Act (1	TAA)?	No					Vial Power Multi			Inner/Carton	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
					Au			orized Generic, other			PHARMACY ORDER	/ BILL UNIT			
	AB						section i	fields are not applicable	Rec. sell unit	to customer?	_	Rx billing ur	nit to pharm	acy:	
II. Generic Equivalent to What Bra	nd?:	Jadenu Sprinkle											Each		
			\\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\						(Write-in, e.g.	. 1 Vial)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION								Milliliter		
Does supplier meet DSCSA definit	ion of manufactur	-0-3	Yes	_	GLN:	0331722000000				ITE	M AND PACKING II	NEORMATION	J		
Is product exempt from DSCSA?	lion of manufactur	err	No	-	GLN.	0331722000000					IN AND I ACKING II	VI OKWATIOI	•		
											D !	(110			
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msm		Volume	Saleable #
Other exemption - Write in: Is product repackaged?			No		¥				Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	aveluciva dietribu	ttor?	Yes	-	direct from m	iginal product purch	naseu		item/Each:	0.15	4	2.13	3.19	27.18	1
Has FDA granted waiver/exception			No	-		ce manufacturer for	ronacka	aged product	Box/Carton/B	tundle/					
If yes, attach documentation from		oudot:			Trovide sour	oc manaractarer for	гораска	agea product	Inner Pack:	dildic/					
yoo, attaon accumontation no.	27								Case:						
		GTI	N AND HIBCC PRODUCT I	NFORMATION						4	12.81	9.85	8.25	1,040.97	12
									Pallet:						
Saleable Unit of Measure	S	Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14							
X Item/Each		1			003	31722029322									
Box/Carton/Bundle/Inner Pack										COST INFORMATION		١	WHOLESAL	ER USE ONL	_Y:
X Case		12			303	31722029323									
Pallet	1								Regular Cost			Vendor #:	_		
									Invoice Cost	(WAC) (\$)	\$1,000.00	Whsl. Code			
	-								An of date:	5/16/2023		Fineline Cod	ae:		
	-								As of date:	3/10/2023					
	1														
 			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter PACKAGE II	INSERT	, LABEL AND PHOTO OF P	BUDITICE BYCK	AGING and BARCODE		!			
		2		0 (0D	_, oon naza	See new p. 3 for D				Signature:					
*Please provide any additional info	ormation on pane														



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For Designated Drop Ship Only Products, Please Use Page 3

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