

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

Version 2021						Introduction Type:	New Item		x Final Version			Date:	6/24/	1/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application:	ANDA	a. Temperatur	re - Indicate the USP tempe	rature range for t	his product			
Application Number for NDA/AN			ce):	21	15534			i i i i i i i i i i i i i i i i i i i	Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applica			·					†	,					
DUNS:	11-856-3719							*	Other Temperature Range I	Requirement	Excursions a	allowed between	en 15°C to 3	0°C (59°F to
Proprietary Name (If Applicable) a	and Established Na	ame: Sapro	pterin Dihydrochloride Table	ts 100 mg				Ţ	(write in)	•	86°F)			
Selling Unit NDC:	31722-045-12		Unit of Use NDC		31722-045-12		722045124	I	Notes					
UDI			CVX Code:			MVX Code:								
Description:	Sapropterin Dihyo	drochloride Tablets 1	00 ma					ī	Is this product to be shipped	to customers on i	ce?		No	1
			9						Is this product to be shipped				No	
Active Ingredient(s):		Sapropterin dihydr	ochloride					†			•			
								b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharm	na.com						Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:		p: 08854		Group E-mail:		somaraju@h	neterousa.cor	<u>n</u>	
Key Contact:	Customer Service	e			Email:	customerservice@can	nberpharma.com							7
Phone Number:	1-866-827-3647	Dhandalada had			Fax:	732-562-8788		c. Special reg	ulations for product in any				No	-
Product Therapeutic Classification	on:	Phenylalanine hyd	roxylase activator						Special returns requirement	s for this product?			No	
	ADDITI	IONAL PROPUST IN	IFORMATION.			PROBLICT RES	ORIETION INCORMATION	ıl.a						7
	ADDITI	IONAL PRODUCT IN	IFURMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only				Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	120 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status				100		Initial shelf life at launch (	f different):				Months
a product kit?		No	EDA Ammercal Status			Strength:	100 mg			ORDER INFORM	AATION			
if yes, list NDCs of component parts			FDA Approval Status				Tablet			ORDER INFORM	IATION			
reverse numbered?		No				Dosage Form:	lablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 1:			
latex-free?		Yes	<b>3</b>				Round		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:			Ampule		, , , ,		,	
correctional institution block?	•	No				Product Color:	Off-white to light yellow,		Glass		Minimum or	rder quantity	?	Yes
opioid?		No				Froduct Color.	mottled		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'I 1' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					1 Toudot Impinio	side & plain on the other		Vial Liquid Multi				ch package	type?
hospital scanning?			Is this product covered						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)?	No				Vial Powder Multi			Inner/Carton	/Pack	
								1	Other: Write In			Case		
			FOR GENERIC DRUG PF	ODUCIS										
					A	horized Generic *If A	Authorized Generic, other		DL	ARMACY ORDER	/ PILL LINIT			
				_	Au		tion fields are not applicable			ARMACT ORDER				
I. Orange Book Rating:	AB	12				300	tion neids are not applicable	Rec. sell unit	to customer?	1	Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	and?:	Kuvan						OM/site in a s	4 \/;e\\			Each		
		DRIIG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION			(Write-in, e.g.	i viai)			Gram Milliliter		
		DR00 3011	ET CHAIN SECONTT ACT	(DSCSA) INI O	KWATION							Willille		
Does supplier meet DSCSA defin	nition of manufactur	irer?	Yes		GLN:	0331722498975			ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No		02	0001122100010								
If ves. select exemption:					GCP:			i		Dimensi	ons (US msn	nts )	Volume	Saleable #
Other exemption - Write in:					GUF.			1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	iginal product purchas	ed	Item/Each:		1	1		I .	
Is product sold by manufacturer's	's exclusive distribu	utor?	Yes	-	direct from m			Luoii.	0.15	1.88	1.88	3.2	11.31	1
Has FDA granted waiver/exception			No	$\neg$		e manufacturer for rep	ackaged product	Box/Carton/B	undle/					
If yes, attach documentation fro	om FDA.							Inner Pack:						
								Case:	4.6	11.75	8	4.5	423.00	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION					4.0	11.70		4.0	420.00	24
								Pallet:						
Saleable Unit of Measure	S	Saleable Quantity	HIBCC		GTII		Unit of Use GTIN-14							
X Item/Each		1			0033	31722045124	00331722045124		COST INFORMATION			WILLOLEO H	ER USE ONL	V
		0.1			2000	31722045128			COST INFORMATION			WHOLESAL	ER USE ONL	100
Box/Carton/Bundle/Inner Pack					2033	01722045128		Regular Cost			Vendor #:			
Box/Carton/Bundle/Inner Pack X Case		24						I Regular Cost						
Box/Carton/Bundle/Inner Pack		24						Invoice Cost	(WAC) (\$)	\$2.240.00		#-		
Box/Carton/Bundle/Inner Pack X Case		24						Invoice Cost (	(WAC) (\$)	\$3,240.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		24							(WAC) (\$)	\$3,240.00				
Box/Carton/Bundle/Inner Pack X Case		24						Invoice Cost (		\$3,240.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		24								\$3,240.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		24	Attach copy of SAFETY D	ATA SHEET (SI	DS) or non hazar	d letter, PACKAGE INSI	ERT, LABEL AND PHOTO OF F	As of date:	1/2/2023	\$3,240.00	Whsl. Code			



## **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?  No	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No  Does the product label bear a CA Prop 65 warning?  No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen 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?	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); SP#	Comments					
ADD'L STORAGE INFORMATION	Registry:  Registry Program Contact Name:  Comments  No  Phone:					
Is the Product						
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No.  No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  I-866-827-3647  Is product returnable for credit:  Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	URL/Link to returns policy:  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)  No  Comments:	If so, which states? Other requirements? Comments?					
MISCELLANE	DUS NOTES and/or Image of Product Barcode:					



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

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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?