

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

Version 2021						Introduction T	Гуре:	New Item		x	Final Version			Date:	2/27/	/2024	
PRODUCT INFORMATION						SPECIAL HANDLING AND STOR				AGE REQUI	REMENTS*						
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/AN			rice):	217	422					Temperati		Controlled Room		and 25 C (68	s° – 77° F)		
Medical Device Class, if applical	ble:																
DUNS:	11-856-3719								,		nperature Range F	Requirement		permitted to 1	5°C to 30°C ((59°F to	
Proprietary Name (If Applicable) a		me: Theor	phylline Extended-Release Ta	blets 450 mg	1	LIDO				(writ	e in)		86°F)				
Selling Unit NDC: UDI	31722-078-01		Unit of Use NDC: CVX Code:			UPC: MVX Code:	331722	2078016		Notes							
						MITA GOGC.			:				_			1	
Description: Theophylline Extended-Release Tablets 450 mg											to customers on in			No No			
Active Ingredient(s): Is this product to be shipped to customers on dry ice? Theophylline (Anhydrous), USP							INO	l									
b. Contact for temperature excursion questions:																	
URL for Additional Product Inform		www.camberpharm								Name:				Soma Raju			
Address: 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:				Number:			732-529-0423						
City: Piscataway			State: Email:	NJ		08854	Group E-mail:				somaraju@l	neterousa.cor	<u>n</u>				
Key Contact: Phone Number:	Customer Service 1-866-827-3647			Fax:	732-562-8788	<u>@Carribe</u>	erpriamia.com	c. Special regulations for product in any states?					No				
Product Therapeutic Classification		Methylxanthine				702 002 0700			Special requirements for this product?				No				
Special returns requirements for this product?																	
	ADDITIC	NAL PRODUCT IN	NFORMATION			PRODUCT	DESCRI	IPTION INFORMATION	d. Store prod	luct (unit of	sale) upright?				No]	
The product is?			Is the Product	Direct-Ship O	nlv				•		roduct (unit of sa	le) from light?			No	1	
a legend device?		No	Is the Product	Neither		0:		100 ct	e. Shelf life:	otoot p	oudor (unit or ou	.o, og			24	Months	
if yes, enter class #			Orphan Drug Status			Size:				Initial she	lf life at launch (i	f different):				Months	
a product kit?		No				Strength:		450 mg					-				
if yes, list NDCs of	FDA Approval Status										ORDER INFORM	IATION					
component parts reverse numbered?		No				Dosage Forn	m:	Tablet		Unit of Sa	ulo.		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present				L				Bottle		1 Bottle of 1		uiiit.		
latex-free?		Yes		C!-		Product Sha		Capsule, bevel edged,			Box/Carton			g. 1 Box of 1	0 Vials)		
preservative-free?		Yes	Dairy, Lact	ose, Casein		Product Sna		biconvex			Ampule						
correctional institution block?		No				Product Cold	or:	White to off white			Glass		Minimum o	der quantity	?	Yes	
opioid? Cannabinoid?		No	Country of Origin	India				Debossed with 'T' and '1'			Γube ∕ial Liquid Sαl						
If Unit Dose, is item bar coded to u		No	Country of Origin	inuia		Product Imp		seperated by a score line on one			/ial Liquid Sgi /ial Liquid Multi		If Yes how	many of whi	ch package	tyne?	
hospital scanning?	unit dose for		Is this product covered u	nder the				side and 'V' on the other side			/ial Powder Sql			Each	on package	type.	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No						/ial Power Multi			Inner/Cartor	/Pack		
	<u>'</u>										Other: Write In			Case			
			FOR GENERIC DRUG PRO	DDUCTS													
											DI.	ADMACY ODDED	/ DULL LINUT				
Authorized Generic *If Authorized Generic, other section fields are not applicable						PHARMACY ORDER / BILL UNIT											
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Theophylline Extended-Release Tablets (Alembic - RS)			Section helds are not applicable			Rec. sell unit to customer?				Rx billing unit to pharmacy:							
II. Generic Equivalent to what Brand?: Theophylline Extended-Release Tablets (Alembic - RS)						(Write-in, e.g. 1 Vial)											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						Milliliter											
Does supplier meet DSCSA defini	ition of manufacture	er?	Yes		GLN:	0331722000000					ITEM	AND PACKING I	NFORMATIO	N .			
Is product exempt from DSCSA? No																	
If yes, select exemption:					GCP:						Weight Lbs.		ons (US msn	•	Volume	Saleable #	
Other exemption - Write in: Is product repackaged?			No		If you was or	iginal product pure	chasad		Item/Each:			Depth	Width	Height	(Cube)	Pieces	
Is product repackaged:	s exclusive distribut	tor?	Yes		direct from m		ciiascu		item/Lacil.		0.3	2.2	2.2	4.75	22.99	1	
Has FDA granted waiver/exception			No			ce manufacturer fo	or repack	kaged product	Box/Carton/E	Bundle/							
If yes, attach documentation from	m FDA.			_					Inner Pack:								
									Case:		8.1	13.5	9.25	5.75	718.03	24	
		GI	TIN AND HIBCC PRODUCT IN	IFORMATION					Pallet:								
Saleable Unit of Measure	Se	aleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14	Pallet:								
X Item/Each	Se	1	TIIDOO			31722078016		Offit of Ose Offit-14									
Box/Carton/Bundle/Inner Pack	Box/Carton/Bundle/Inner Pack						COST INFORMATION WHOLESALER USE ONLY:					.Y:					
X Case		24			203	31722078010											
Pallet	-						_		Regular Cos				Vendor #:				
	-								Invoice Cost	(WAC) (\$)		\$300.00	Whsl. Code Fineline Co				
									As of date:	П			i illeline Co	uc.			
									, 10 0, date.				1				
	_						_										
*Please provide any additional inf			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza			T, LABEL AND PHOTO OF F	RODUCT PACK	AGING and	BARCODE.						



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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? 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?	SDS Hazard Classification x Organic Corrosive 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? Is this product regulated for shipment by DOT?	identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? No						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	If yes, indicate which: 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) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	REMS or REGISTRY RESTRICTIONS 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#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments 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)? ARCOS Reportable? Schedule No. 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: 1-866-827-3647 Yes						
	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Ye	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No.	product in certain states? If so, which states? Other requirements? Comments?						
Comments:							
MISCELL	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?						