

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

Version 2024						Introduction Type:	New Item	х	Final Version			Date:	10/29	/2024
			PRODUCT INFORMAT	TION					SPECIAL HAND	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	Camber Pharmac	euticals. Inc.				Application:	ANDA	a. Temperature – Indica	te the USP temper	rature range for th	is product.			
Application Number for NDA/ANI	DA/BLA: PMA/510	(k): 217	7422			NDA 505(b) Type:	NOT APPLICABLE			Controlled Room -		and 25 C (68°	° – 77° F)	
Medical Device Class, if applicab		(,-				(., ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				-		(
DUNS:	11-856-3719							Other Ter	mperature Range R	equirement	Excursions p	ermitted to 15	5°C to 30°C (59°F to
Proprietary Name (If Applicable) as		me: The	eophylline Extended-Release Ta	ablets 450 mg					te in)		86°F)			
Selling Unit NDC:	31722-078-01		Unit of Use NDC:			UPC: 3317	22078016	Notes	,					
UDI			CVX Code:			MVX Code:								
Description:	Theophylline Exte	ndod Bologoo Tol	bloto 450 mg					lo this pro	oduct to be shipped	to quotomore on in	2		No	
Description.	Theophylline Exte	nucu-ivelease rai	blets 400 mg						oduct to be shipped				No	
Active Ingredient(s):		Theophylline (Ar	nhydrous). USP					is this pro	oddot to be shipped	to customers on a	y 100 :	Į.	140	
, tour o mg. outoni(o).		Thoophymno (7 ti	, a. 5 a.5, 5 c.					b. Contact for temperat	ure excursion que	stions:				
URL for Additional Product Inform	ation:	www.camberpha	rma.com					Name:			Soma Raju			
Address:	800 Centennial Av		·			Address 2:		Number:			732-529-042	3		
City:	Piscataway				State:	NJ Zip:	08854	Group E-	-mail:		somaraju@h	eterousa.com	<u>1</u>	
Key Contact:	Customer Service				Email:	customerservice@camb		·						
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for	or product in any s	states?			No	
Product Therapeutic Classification):	Methylxanthine b	oroncodilator					Special re	eturns requirements	for this product?			No	
	ADDITI	ONAL PRODUCT	INFORMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store product (unit o	f sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nlv			Protect of	product (unit of sal	e) from light?		Ī	No	
a legend device?		No	Is the Product	Neither			100 ct	e. Shelf life:		-, .			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:	1000		elf life at launch (if	different):				Months
a product kit?	1	No	. ,			a	450 mg			,				
if yes, list NDCs of			FDA Approval Status			Strength:	3			ORDER INFORM	ATION			
component parts			•			Danama Farmi	Uncoated, extended-							
reverse numbered?		No				Dosage Form:	release tablet	Unit of S	ale		What is the I	NDC selling	unit?	
co-licensed?		No	Allergens Present					x	Bottle		1 Bottle of 10	0 Tablets		
latex-free?		Yes	Dairy Lact	ose, Casein		Product Shape:	Capsule, bevel edged,		Box/Carton		(Write-in, e.g	. 1 Box of 10	Vials)	
preservative-free?		Yes	Daii y, Lact	ose, Caselli		r roduct onape.	biconvex		Ampule					
correctional institution block?		No				Product Color:	White to off-white		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'T' and '1' separated by a score line on one side and 'V' on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for						the other side		Vial Liquid Multi		If Yes, how I	nany of whice	ch nackage t	
							the other side						paonago i	ype?
hospital scanning?			Is this product covered u				the other side		Vial Powder Sgl		24	Each		ype?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (T		No		the other side		Vial Powder Sgl Vial Powder Multi		24	Each Inner/Carton/		ype?
			Trade Agreements Act (T	ΓΑΑ)? [No		(ine other side		Vial Powder Sgl		24	Each		sype?
				ΓΑΑ)? [No		line other side.		Vial Powder Sgl Vial Powder Multi		24	Each Inner/Carton/		ype?
			Trade Agreements Act (T	ΓΑΑ)? [therized Conorio *16 Au			Vial Powder Sgl Vial Powder Multi Other: Write In		24	Each Inner/Carton/		ype?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	ΓΑΑ)? [uthorized Generic, other		Vial Powder Sgl Vial Powder Multi Other: Write In	ARMACY ORDER	24 / BILL UNIT	Each Inner/Carton/ Case	Pack	ype?
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If Unit Dose, indicate NDC here:			Trade Agreements Act (T	ODUCTS	Au		uthorized Generic, other	Rec. sell unit to custom (Write-in, e.g. 1 Vial)	Vial Powder Sgl Vial Powder Multi Other: Write In		24 / BILL UNIT	Each Inner/Carton/ Case it to pharma Each Gram	Pack	ype?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	ODUCTS	Au		uthorized Generic, other	Rec. sell unit to custom	Vial Powder Sgl Vial Powder Multi Other: Write In		24 / BILL UNIT	Each Inner/Carton/ Case it to pharma Each	Pack	ype?
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bran	nd?:	DRUG SUF	Trade Agreements Act (T FOR GENERIC DRUG PRO PPLY CHAIN SECURITY ACT (ODUCTS DSCSA) INFORI	Au	section	uthorized Generic, other	Rec. sell unit to custom (Write-in, e.g. 1 Vial)	Vial Powder Sgl Vial Powder Multi Other: Write In PHA ner?	ARMACY ORDER	/ BILL UNIT	Each Inner/Carton/ Case it to pharma Each Gram Milliliter	Pack	ype?
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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	Trazardous Waste identification					
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	, NO					
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)

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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: 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?