

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

Version 2024						Introduction Ty	pe: New Item		x Final Version			Date:	11/7	/2024
			PRODUCT INFORMAT	TION					SPECIAL HAP	NDLING 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	IDA/BLA; PMA/510	O(k): 214321				NDA 505(b) Type:	NOT APPLICABLE	Ten	nperature Range	Controlled Room -	- between 20	and 25 C (68	s° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719							Oth	er Temperature Range	Requirement	Excursions p	permitted to 1	5° to 30°C (5	9° to 86°F)
Proprietary Name (If Applicable) a		ame: Posaco	nazole Delayed-Release Ta	blets 100 mg					(write in)					
Selling Unit NDC:	31722-677-60		Unit of Use NDC:		31722-677-60		331722677608	Not	es					
UDI			CVX Code:			MVX Code:								
Description:	Posaconazole De	elayed-Release Tablets	s 100 mg						nis product to be shippe				No	
								Is th	nis product to be shippe	d to customers on d	ry ice?		No	
Active Ingredient(s):		Posaconazole						h Contact for tom	perature excursion qu	octions:				
URL for Additional Product Inform	nation:	www.camberpharma	com					b. Contact for tem		iestions:	Soma Raju			
Address:	800 Centennial A					Address 2:			nber:		732-529-042	23		
City:	Piscataway				State:	NJ	Zip: 08854	_	oup E-mail:		somaraju@h	neterousa.cor	<u>n</u>	
Key Contact:	Customer Service	e			Email:		camberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788			ons for product in any				No	
Product Therapeutic Classification	on:	Azole antifungal						Spe	ecial returns requiremen	its for this product?			No	
			A DATA TION											1
	ADDIII	IONAL PRODUCT INF				PRODUCT DE	ESCRIPTION INFORMATION	<b>-</b>	unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only				tect product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	60 ct	e. Shelf life:	tal abalfille at lassach	('e -1'ee			24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				100 mg	.	ial shelf life at launch	(if different):				Months
if yes, list NDCs of		140	FDA Approval Status			Strength:	100 mg			ORDER INFORM	IATION			
component parts			,,			Dosage Form:	Delayed-release, film-							
reverse numbered?		No				Dosage Form.	coated tablet		t of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present					.	x Bottle		1 Bottle of 6			
latex-free?		Yes	Alc	ohol		Product Shape	Oblong e:		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes No					Light orange		Ampule Glass		Minimum o	rder quantity	12	Yes
opioid?		No				Product Color	: Light Grange		Tube		William Ci	uei quantity	•	163
Cannabinoid?		No	Country of Origin	India		Due de cet les mais	Debossed 'H' on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					Product Impri	'P11' on the other side		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered up						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	'AA)?	No				Vial Powder Multi			Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCIS										
					Aı Aı	uthorized Generic	*If Authorized Generic, other		PI	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit to cu				nit to pharm	acv:	
II. Generic Equivalent to What Bra		Noxafil		_				Tico: sen unit to et	astomer.		IXX billing u	Each	acy.	
								(Write-in, e.g. 1 Vi	al)			Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT (I	DSCSA) INFO	RMATION			HCPCS J-Code:				Milliliter		
		_		_										
Does supplier meet DSCSA defini	ition of manufactu	irer?	Yes No	_	GLN:	0331722498975			IIE	M AND PACKING IN	IFORMATIO	N		
Is product exempt from DSCSA?			IVU											
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msn		Volume	Saleable #
Other exemption - Write in: Is product repackaged?			No		If you was a	riginal product purch	nased	Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product repackaged:	s exclusive distrib	utor?	Yes	-	direct from n		laseu	item/Lacii.	0.17	1.87	1.87	4	13.99	1
Has FDA granted waiver/exceptio			No	1			repackaged product	Box/Carton/Bundl	e/					
If yes, attach documentation fro	m FDA.							Inner Pack:						
								Case:	4.6	11.75	8	5.13	482.22	24
		GTIN	I AND HIBCC PRODUCT IN	IFORMATION				B-II-4		-				
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		CTI	IN-14	Unit of Use GTIN-14	Pallet:						
Saleable Offit of Measure	KFID tag(1/N)	Quantity	ПІВСС		GII	IIN-14	Offit of Ose G11N-14							
x Item/Each	N	1 1			003	331722677608	00331722677608	111						
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	_Y:
X Case	N	24			203	331722677602								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WAC	J) (\$)	\$450.00	Whsl. Code Fineline Co			
								As of date:	5/30/2023		i illeline Co	uc.		
								7.0 0. 3010.	3. 23. 2020		1			
											<u> </u>			
			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza	ard letter, PACKAGE II	NSERT, LABEL AND PHOTO OF	PRODUCT PACKAGIN	G and BARCODE.					
*Please provide any additional inf	formation on page	2.				See new p. 3 for D	esignated Drop Ship Only.	Sig	nature:					



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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?	1						
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						
, ,	DEMS of DECISTOR DESTRICTIONS						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or 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?					