

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

Version 2024						Introduction T	ype: New Item	x	Final Version			Date:	3/17/	2025	
			PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.					Applicat	ion: ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANI	DA/BLA; PMA/510	(k): 2190	057			NDA 505(b) Type:	NOT APPLICABLE		rature Range	Cold – between 2		- 46° F)			
Medical Device Class, if applicab	ole:														
DUNS:	11-856-3719							Other 7	Γemperature Range Ι	Requirement	Once admixed, the dilute used immediately. If not	d solution of posaconazo used immediately, the sol	le in the intravenous bag i ution can be stored up to 2	or bottle) should be 24 hours refrigerated 2	
Proprietary Name (If Applicable) a		ame: Posa	aconazole Injection 300 mg/16.	7 mL (18 mg/m	L) Single-Dose				write in)						
Selling Unit NDC:	31722-370-31		Unit of Use NDC:			UPC:	331722370318	Notes			*To be shipped	o customers usi	ng proper cold st Storage Trucks)	orage shipping	
UDI			CVX Code:			MVX Code:					metrious (e.g. C	olu i acks, colu			
Description:	Posaconazole Inj	ection 300 mg/16.7	mL (18 mg/mL) Single-Dose V	ial					product to be shipped				No*		
Is this product to be s									product to be shipped	d to customers on o	Iry ice?		No		
Active Ingredient(s):		Posaconazole						h Comtont for towns							
URL for Additional Product Inform	ation:	www.cambernham	ma com					b. Contact for temper Name:	ature excursion qu	estions:	Soma Raju				
Address:		www.camberpharma.com htennial Ave, Suite 1			Address 2:			Number: 732-529-0423							
City:	Piscataway					NJ	Zip: 08854				somaraju@heterousa.com				
Key Contact:	Customer Service	9			Email:	customerservice@	camberpharma.com	·							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations	s for product in any	states?			No		
Product Therapeutic Classification	n:	Azole antifungal						Specia	I returns requirement	s for this product?			No		
					_			_							
	ADDITI	ONAL PRODUCT I	NFORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store product (uni	t of sale) upright?				No		
The product is?			Is the Product	Direct-Ship C	Only	1			t product (unit of sa	le) from light?			No		
a legend device?		No	Is the Product	Unit Dose		Size:	16.7 mL single dose vial	e. Shelf life:					24	Months	
if yes, enter class #		la.	Orphan Drug Status				000	Initial	shelf life at launch (if different):				Months	
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	300 mg/16.7 mL (18 mg/mL) per single dose vial			ORDER INFORM	MATION				
component parts			PDA Approvai Status				Clear sterile solution			ORDER IN ORI	IATION				
reverse numbered?		No				Dosage Forn	n:	Unit of	Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present						Bottle		1 Carton of 1				
latex-free?		Yes		disodium		Product Sha	N/A	x	Box/Carton			g. 1 Box of 10			
preservative-free?		No	Luciale	uisouiuiii		r roudet Sna			Ampule						
correctional institution block?		No				Product Cold	Colorless to yellow	x	Glass		Minimum or	der quantity	?	Yes	
opioid?		No		L. P.					Tube						
Cannabinoid? If Unit Dose, is item bar coded to u	unit alana fau	No	Country of Origin	India		Product Impi	rint: N/A	x	Vial Liquid Sgl Vial Liquid Multi		K Vaa haw		ch package t		
hospital scanning?	mit dose for	Yes	Is this product covered u	nder the					Vial Powder Sgl			Each	сп раскаде т	ype r	
If Unit Dose, indicate NDC here:		31722-370-31	Trade Agreements Act (T		No				Vial Powder Multi			Inner/Carton	/Pack		
			,	*					Other: Write In			Case			
			FOR GENERIC DRUG PRO	DDUCTS											
											-				
				_	Au	thorized Generic	*If Authorized Generic, other section fields are not applicable			ARMACY ORDER					
	AP						section fields are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Noxafil						Each									
		DRUG SUP	PLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			(Write-in, e.g. 1 Vial) HCPCS J-Code:				Gram Milliliter			
			,	, ,	-					1					
Does supplier meet DSCSA definit	tion of manufactu	rer?	Yes		GLN:	0843368117603			ITEN	AND PACKING I	NFORMATION				
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:				Weight Lbs.	Dimensi	ons (US msm	its.)		Saleable #	
Other exemption - Write in:			.,							Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No	_		riginal product pure	hased	Item/Each:	0.12	1.65	1.65	2.76	7.51	1	
Is product sold by manufacturer's Has FDA granted waiver/exception			Yes No	+	direct from m		r repackaged product	Box/Carton/Bundle/							
If yes, attach documentation from		oddct?	110		Flovide Soul	ce manuracturer 10	repackaged product	Inner Pack:							
,,								Case:	13.17	14.17	11.02	6.69	1044.67	96	
		G ⁻	TIN AND HIBCC PRODUCT IN	IFORMATION					13.17	14.17	11.02	0.09	1044.67	96	
					0.77			Pallet:							
						N-14	Unit of Use GTIN-14								
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		011										
		Quantity	HIBCC			31722370318									
Saleable Unit of Measure x	RFID tag(Y/N)		нівсс			31722370318			ST INFORMATION			WHOL <u>ESALI</u>	ER USE ONL	Y:	
x Item/Each		Quantity	HIBCC		003	31722370318		CO	ST INFORMATION			WHOLESALI	ER USE ONL	Y :	
x Item/Each Box/Carton/Bundle/Inner Pack	N	Quantity 1	HIBCC		003			Regular Cost			Vendor #:		ER USE ONL	Y:	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	N	Quantity 1	HIBCC		003					\$270.00	Vendor #: Whsl. Code	#:	ER USE ONL	Y:	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	N	Quantity 1	HIBCC		003			Regular Cost Invoice Cost (WAC) (\$)	\$270.00	Vendor #:	#:	ER USE ONL	Y:	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	N	Quantity 1	HIBCC		003			Regular Cost		\$270.00	Vendor #: Whsl. Code	#:	ER USE ONL	Y:	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	N	Quantity 1	HIBCC		003			Regular Cost Invoice Cost (WAC) (\$)	\$270.00	Vendor #: Whsl. Code	#:	ER USE ONL	Y:	
X Item/Each Box/Carton/Bundle/Inner Pack X Case	N	Quantity 1		TA SHEET (SC	203	31722370312	INSERT, LABEL AND PHOTO OF	Regular Cost Invoice Cost (WAC) (As of date:	3/13/2025	\$270.00	Vendor #: Whsl. Code	#:	ER USE ONL'	Y:	



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD 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? 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 e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
ls this product regulated for shipment by IATA?	EFA Hazaiuous waste Code.					
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number 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#: 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? 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	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: Yes					
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: Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?					
Comments:						
MISCELLAN	EOUS 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 Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight receipt available:
Drop Ship service fee billed with each order:	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, 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:	Saturday Overnight receipt available: PO Receipt Cut off time: 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/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?