

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

Version 2021						Introduction Ty	pe: New Item		x Final Version			Date:	10/31	1/2022
			PRODUCT INFORMAT	TION					SPECIAL HAP	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Appl				Application	n: ANDA	a. Temperati	ure - Indicate the USP temp	erature range for t	his product.					
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212674			2674				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:														
DUNS:	82-677-4775								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) as	nd Established Na	me: Pirfer	nidone Tablets 267mg 270ct (3x90ct)					(write in)	•				
Selling Unit NDC:	31722-872-27		Unit of Use NDC:				31722872270		Notes					
UDI			CVX Code:			MVX Code:								
Description: Oral Solid - Tablet, oval, white, Upper: 'P 16' Lower: 'H' Is this product to be shipped to customers on ice? No									1					
•									Is this product to be shippe				No	
Active Ingredient(s):		Pirfenidone												
						b. Contact fo	or temperature excursion qu	estions:						
URL for Additional Product Inform									Name:		Soma Raju			
Address:		Ave (and) 800 Cente	nnial Ave, Suite 1			Address 2:			Number:		732-529-042			
City:	Piscataway				State:		Zip: 08854	Group E-mail: somaraju@heterc			heterousa	.com		
Key Contact:	Customer Service 1-866-827-3647					732-562-8788	@camberpharma.com	c. Special regulations for product in any states?				NI.	1	
Phone Number:		Butters			Fax:	132-302-0100		c. Special re					No	
Product Therapeutic Classification	1:	Pyridones							Special returns requiremen	ts for this product?			No	
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?														
	ADDITIO	UNAL PRODUCT II				PRODUCT DE	SCRIPTION INFORMATION	a. Store prod	duct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	only				Protect product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product			Size:	270ct (3x90ct)	e. Shelf life:					24	Months
if yes, enter class #		1	Orphan Drug Status					_	Initial shelf life at launch	(if different):				Months
a product kit?		No	FDA Ammerical Status			Strength:	267mg			ORDER INFOR	MATION			
if yes, list NDCs of component parts			FDA Approval Status				Oral Solid - Tablet			OKDEK INFORI	MATION			
reverse numbered?		No				Dosage Form:	Oral Solid - Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					-	Bottle		1 bottle of 27			
latex-free?		Yes					Oval		1 Box/Carton			g. 1 Box of 1		
preservative-free?		Yes				Product Shape	:		Ampule		, , , , ,	5	,	
correctional institution block?		No				Product Color	White		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Color	•		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprir	Upper: 'P 16' Lower: 'H'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					oddotp			Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?		No	Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No				Vial Power Multi Other: Write In			Inner/Carton	/Pack	
									Other: write in			Case		
			FOR GENERIC DRUG PRO	DDUCIS										
					Δ.,	thorized Generic *	If Authorized Generic, other		Pi	HARMACY ORDER	/ BILL LINIT			
	4.0			_			ection fields are not applicable	Dec cell uni	t to customer?	IARINAOT ORDER				
	AB	Esbriet						Rec. sell uni	t to customer?		Rx billing ui	nit to pharma	acy:	
II. Generic Equivalent to What Bran	na /:	Espriet						(Write-in, e.g	1 1 \/ial\			Each Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFOR	MATION			(vviite-iii, e.g	j. i viaij			Milliliter		
			- , , , , , , , , , , , , , , , , , , ,											
Does supplier meet DSCSA definit	ion of manufactur	er?	Yes	7	GLN:	0331722000000			ITE	M AND PACKING I	NFORMATION	١		
Is product exempt from DSCSA?		i i	No											
If ves. select exemption:				_	GCP:					Dimens	ions (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product purch	ased	Item/Each:	0.35	5.125	1.75		· ,	
Is product sold by manufacturer's	exclusive distribu	itor?	Yes		direct from m			_	0.35	5.125	1.75	3.5		1
Has FDA granted waiver/exception	/exemption for pr	oduct?	No		Provide sour	ce manufacturer for	repackaged product	Box/Carton/	Bundle/					
If yes, attach documentation fron	n FDA.							Inner Pack:						
								Case:	3.4	11.5	8	4.5		8
		GT	IN AND HIBCC PRODUCT IN	NFORMATION										
Saleable Unit of Measure					0.77			Pallet:						
X Item/Each	S	aleable Quantity	HIBCC			N-14 31722872270	Unit of Use GTIN-14 00331722872270							
Box/Carton/Bundle/Inner Pack		-			003	31122012210	00331122012210		COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		8			203	31722872274			- COOT INTORMATION			OLICAL	OOL ONL	
Pallet					200			Regular Cos	t		Vendor #:			
	1							Invoice Cost		\$1,800.00	Whsl. Code	#:		
]							- [1]			Fineline Co			
]							As of date:						
								- [1]						
1											<u> </u>			
l		_	Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza		NSERT, LABEL AND PHOTO C	F PRODUCT PACK						
*Please provide any additional info	rmation on nage	2				See new p. 3 for D	esignated Drop Ship Only.		Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL 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? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? 	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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class		Hazardous Waste Identification				
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics			
Is this product regulated for shipment by IATA?	No		· · · · · · · · · · · · · · · · · · ·			
(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	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No			
e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Passenger & Cargo 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);		Comments				
SP#		Registry: Registry Program Contact Name:	No	Phone:		
ADD'L STORAGE INFORMATION		Comments				
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	No	RE	ETURN INSTRUCTIONS			
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 Yes			
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:	No No	Special regulations or returns requirements for this product in certain states?				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	product in certain states? No If so, which states? Other requirements? Comments?					
Comments:						
	SCELLANEO	US 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?				