

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

Version 2021						Introduction Ty	уре:	Post Launch Change		x Final Version			Date:	8/11	1/2024
			PRODUCT INFORMA	TION						SPECIAL HA	NDLING AND STO	RAGE REQUIF	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 090060			0060				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:															
DUNS:	11-856-3719									Other Temperature Range	Requirement				
Proprietary Name (If Applicable) as	nd Established Na	ame: Finas	teride Tablets, USP 1 mg							(write in)	•				
Selling Unit NDC:	31722-526-90		Unit of Use NDC:		31722-526-90		33172252	6906		Notes					
UDI			CVX Code:			MVX Code:									
Description: Finasteride Tablets, USP 1 mg Is this product to be shipped to customers on ice? No								1							
		.,								Is this product to be shippe				No	1
Active Ingredient(s):		Finasteride, USP										•			_
							b. Contact fo	temperature excursion q	uestions:						
URL for Additional Product Inform		www.camberpharm	na.com							Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:				Number:		732-529-042			
City:	Piscataway				State:	NJ Zip: 08854				Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service					customerservice@camberpharma.com 732-562-8788									7
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special reg	julations for product in an				No	-
Product Therapeutic Classification	1:	5 alpha-reductase	inhibitor							Special returns requirement	nts for this product?			No	
	ADDITI	ONAL PRODUCT IN	NFORMATION			PRODUCT D	DESCRIPTI	ION INFORMATION	d. Store prod	uct (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	Unit of Use		Size:	90	ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.				Initial shelf life at launch	(if different):				Months
a product kit?		No				Strength:	1 n	ng							
if yes, list NDCs of			FDA Approval Status				_				ORDER INFOR	MATION			
component parts		1				Dosage Form	ı: Filr	m coated tablet		Helicat Octo		\A/h a4 ia 4h a	NDC a allian		
reverse numbered?		No	Allermana Brasant							Unit of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Do	und		x Bottle Box/Carton		1 Bottle of 9	g. 1 Box of 1	O \/iolo\	
preservative-free?		Yes	Dairy, Lactose, D	ye, Corn, Alco	hol	Product Shap	oe:	unu		Ampule		(vviite-iii, e.	y. 1 bux 01 1	U Viais)	
correctional institution block?		No					Bro	own		Glass		Minimum or	der auantity	12	Yes
opioid?		No				Product Color	r:	JWII		Tube			uci quaintity	•	103
Cannabinoid?		No	Country of Origin	India			. Del	bossed with 'H' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		, 3			Product Impri	int: side	e and '36' on the other		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (AA)?	No					Vial Powder Mult	i		Inner/Cartor	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
												_			
					Auth			zed Generic, other		Р	HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB						section fie	elds are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bran	nd?:	Propecia											Each	,	
-									(Write-in, e.g	1 Vial)	_		Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION								Milliliter		
				_											
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes		GLN:	0331722498975				ITE	M AND PACKING I	NFORMATION	1		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:										weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			ginal product purcl	hased		Item/Each:	0.08	1.6	1.6	3.14	8.04	1
Is product sold by manufacturer's			Yes		direct from mf							1.0	0	0.01	· ·
Has FDA granted waiver/exception		roduct?	No		Provide source	e manufacturer for	r repackag	jed product	Box/Carton/E	undle/					
If yes, attach documentation from	n FDA.								Inner Pack:						
		CT.	IN AND HIBCC PRODUCT II	JEODMATION					Case:	2.25	9.75	6.75	4.25	279.70	24
		GI	IN AND HIBCC PRODUCT II	NFORMATION					Dellet			-			
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTIN	14		Init of Use GTIN-14	Pallet:						
x Item/Each	3	1	ПВСС			1722526906		0331722526906							
Box/Carton/Bundle/Inner Pack		-			0033		0	0001122020000		COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case		24			2033	1722526900									
Pallet									Regular Cost			Vendor #:			
	1								Invoice Cost		\$12.00	Whsl. Code	#:		
]						1					Fineline Co			
									As of date:	12/1/2024					
1									<u> </u>			<u> </u>			
			Attach copy of SAFETY DA	TA SHEET (SE	S) or non hazard				RODUCT PACK	AGING and BARCODE.					
*Please provide any additional info						See new p. 3 for D	D ! ! -	d David Oblin Oak		Signature:					



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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?	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? No	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: Yes Group 3 items (primarily adverse reproductive effects)						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics						
(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 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#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments						
SP#	Registry: No Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION Is the Product	Comments						
Controlled Substance? 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 CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No	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? No If so, which states? Other requirements? Comments?						
Comments:							
MISCELLA	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?