

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

Version 2024						Introduction Type	: New Item		x Final Version			Date:	3/11/	/2025
			PRODUCT INFORMAT	ION					SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application:	ANDA	a. Temperature	- Indicate the USP temper	erature range for th	nis product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	O(k): 090060				NDA 505(b) Type:	NOT APPLICABLE		emperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat									,					
DUNS:	11-856-3719							C	Other Temperature Range I	Requirement				
Proprietary Name (If Applicable) a		ame: Finaster	ide Tablets, USP 1 mg						(write in)					
Selling Unit NDC:	31722-526-90		Unit of Use NDC:		31722-526-90		1722526906	, N	lotes					
UDI			CVX Code:			MVX Code:								
Description:	Finasteride Table	ets, USP 1 mg						Is	s this product to be shipped	d to customers on ic	e?		No	
								Is	s this product to be shipped	d to customers on d	ry ice?		No	
Active Ingredient(s):		Finasteride, USP												
URL for Additional Product Inform		www.camberpharma.c							emperature excursion qu	estions:	Soma Raju			
Address:	800 Centennial A		COM		I	Address 2:			lame: lumber:		732-529-042	3		
City:	Piscataway	ive, Juile 1			State:		p: 08854		Group E-mail:			eterousa.con)	
Key Contact:	Customer Service								oup = mam				-	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regul	ations for product in any	states?			No	1
Product Therapeutic Classification	n:	5 alpha-reductase inh	nibitor					s	special returns requirement	ts for this product?			No	
	ADDIT	IONAL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	nly			P	rotect product (unit of sa	ale) from light?			No	i
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			Size:		lı lı	nitial shelf life at launch (if different):				Months
a product kit?		No				Strength:	1 mg							
if yes, list NDCs of			FDA Approval Status			g				ORDER INFORM	IATION			
component parts		NI.				Dosage Form:	Film coated tablet		Init of Sale		What is the	NDC selling	unit?	
reverse numbered? co-licensed?		No No	Allergens Present					1	x Bottle		1 Bottle of 90		umr	
latex-free?		Yes					Round		Box/Carton			g. 1 Box of 10	(Vials)	
preservative-free?		Yes	Dairy, Lactose, Dy	ye, Corn, Alco	hol	Product Shape:	rtouria		Ampule		(**************************************	g. 1 Don 01 11	· · · · · · · · · · · · · · · · · · ·	
correctional institution block?		No				Product Color:	Brown		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'H' on one side and '36' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for						30 Oil the other side		Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered un					_	Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA	AA)?	No			-	Vial Powder Multi Other: Write In			Inner/Carton Case	Pack	
			FOR GENERIC DRUG PRO	PLIOTO					Other, write in			Case		
			FOR GENERIC DRUG PRO	DDUCIS										
					Δur	thorized Generic *If	Authorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I Oranga Baak Batings	AB			Т	710		ction fields are not applicable	Rec. sell unit to						
I. Orange Book Rating: II. Generic Equivalent to What Brai		Propecia						Rec. sen unit to	customerr	1	KX billing ui	nit to pharma Each	cy:	
ii. Generic Equivalent to What Bra	iiu:.	Порсска						(Write-in, e.g. 1	Vial)			Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (D	OSCSA) INFOR	MATION			HCPCS J-Code:				Milliliter		
Does supplier meet DSCSA definit	tion of manufactu	rer?	Yes		GLN:	0331722498975			ITEN	AND PACKING IN	IFORMATION	1		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.	Dimension	ons (US msm	ıts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purchas	sed	Item/Each:	0.08	1.6	1.6	3.14	8.04	1
Is product sold by manufacturer's			Yes No	-	direct from m			D /O /- /- /D						
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	INU		Provide source	e manufacturer for re	раскадей ргодист	Box/Carton/Bur Inner Pack:	iale/					
ii yes, attacii documentation noi	III DA.							Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION				Ousc.	2.25	9.75	6.75	4.25	279.70	24
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GTIN-14							
		Quantity												
x Item/Each	N	1			0033	31722526906	00331722526906		OCCUPATION OF THE PERSON OF TH			MIIOI EAVE	D HOE eve	V
Box/Carton/Bundle/Inner Pack	N	24				24722526000			COST INFORMATION			WHOLESAL	R USE ONL	.Y:
X Case	N	24			2033	31722526900		Regular Cost			Vendor #:			
1 canot								Invoice Cost (W	AC) (\$)	\$12.00	Whsl. Code	#:		
										Ψ.2.50	Fineline Cod			
								As of date:	12/1/2024]			
											1			
*Please provide any additional info			Attach copy of SAFETY DAT	TA SHEET (SD	S) or non hazar		ERT, LABEL AND PHOTO OF P		ING and BARCODE.					



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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? 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? No Does the product label bear a CA Prop 65 warning? 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?	SDS Hazard Classification X Organic Corrosive Oxidizer Contact Hazard 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 e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	REMS or REGISTRY RESTRICTIONS 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) Special Permit; DOT-SP	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 Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION Is the Product Controlled Substance? No Controlled Substance Code	Comments RETURN INSTRUCTIONS					
Controlled by State(s)? ARCOS Reportable? No Schedule No. Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: 1-866-827-3647 Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No Comments:	product in certain states? If so, which states? Other requirements? Comments?					
	DUS NOTES and/or Image of Product Barcode: or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus.					



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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?					