

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

Version 2021						Introduction	Type: F	Post Launch Change	x	Final Version			Date:	8/11/	/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STOP	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceutical	ls. Inc.				Applica	ation:	ANDA	a. Temperature – Ind	icate the USP temp	erature range for t	his product.			
Application Number for NDA/ANI			a):	090	0060					rature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab			,						· ·						
DUNS:	11-856-3719								Other	Femperature Range	Requirement				
Proprietary Name (If Applicable) a		Finaste	ride Tablets, USP 1 mg						[write in)					
Selling Unit NDC:	31722-526-30		Unit of Use NDC:		31722-526-30		331722526	302	Notes						
UDI			CVX Code:			MVX Code:									
Description:	Finasteride Tablets, USF	P1mg							Is this	product to be shippe	d to customers on i	ce?		No	1
Is this product to be shipped to customers on dry ice? No]							
Active Ingredient(s): Finasteride, USP															
								b. Contact for tempe		estions:	a a i				
URL for Additional Product Inform Address:		.camberpharma	<u>com</u>		1	Address 2:			Name			Soma Raju 732-529-042	2		
City:	800 Centennial Ave, Suite 1 Piscataway State:			NJ	Zip: 08	854	Numb	E-mail:		somaraju@heterousa.com					
Key Contact:	Customer Service Email:			customerservice			Group	E man.							
Phone Number:	1-866-827-3647				732-562-8788				s for product in any	states?			No	1	
Product Therapeutic Classification	n: 5 alp	ha-reductase in	hibitor						Special returns requirements for this product? No					1	
•••••					1										1
	ADDITIONAL	PRODUCT INF				PRODUCT	DESCRIPTIC	ON INFORMATION	d. Store product (uni	t of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	nly				1	t product (unit of s	ale) from light?			No	1
a legend device?	No		Is the Product	Unit of Use		C i= -	30 c	t	e. Shelf life:	, (unit of o	,			24	Months
if yes, enter class #			Orphan Drug Status			Size:				shelf life at launch ((if different):				Months
a product kit?	No					Strength:	1 mg	g							4
if yes, list NDCs of			FDA Approval Status			Suengui.					ORDER INFORM	IATION			
component parts						Dosage For	m: Film	coated tablet							
reverse numbered?	No		All			-			Unit o			What is the		unit?	
co-licensed? latex-free?	No		Allergens Present				Rou	nd	x	Bottle Box/Carton		1 Bottle of 3	g. 1 Box of 10) \/iolo)	
preservative-free?	Yes		Dairy, Lactose, D	Dye, Corn, Alco	hol	Product Sha	ape:	nu		Ampule		(winte-in, e.	g. I DOX OF I	/ viais)	
correctional institution block?	No						Brov	wn		Glass		Minimum or	der quantity	?	Yes
opioid?	No					Product Col	lor:			Tube			,		
Cannabinoid?	No		Country of Origin	India		Product Imp		ossed with 'H' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for					riouucimp	side	and '36' on the other		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u							Vial Powder Sgl		24	Each	_ .	
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	No					Vial Powder Multi			Inner/Carton	Pack	
			FOR GENERIC DRUG PR							Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS											
					Au	thorized Generic	*If Authoriz	ed Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB			-	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			ds are not applicable	Rec. sell unit to cust				ait to phorm	-	
II. Generic Equivalent to What Brai		ecia							Rec. sell unit to customer? Rx billing unit to pharmacy Each				icy.		
								(Write-in, e.g. 1 Vial) Gram							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION															
Does supplier meet DSCSA definit	tion of manufacturer?		Yes	_	GLN:	0331722498975				ITEN	I AND PACKING I	NFORMATION	1		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msm	-	Volume	Saleable #
Other exemption - Write in:			Ne								Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	avelueius distributer?		No	_		iginal product pur	rchased		Item/Each:	0.06	1.5	1.5	3	6.75	1
Is product sold by manufacturer's Has FDA granted waiver/exception		2	Yes		direct from m	rr? ce manufacturer fo	or renackage	ed product	Box/Carton/Bundle/						
If yes, attach documentation from		•			Troviac Sour		orrepuenage	a product	Inner Pack:						
··· , ··· · · · · · · · · · · · · · · · · ·									Case:	2	9.5	0.5	4	247	24
		GTIN	AND HIBCC PRODUCT II	NFORMATION						2	9.5	6.5	4	247	24
									Pallet:						
Saleable Unit of Measure	Saleabl	e Quantity	HIBCC			N-14		it of Use GTIN-14							
X Item/Each		1			003	31722526302	00	331722526302					WHOLESALI		V
Box/Carton/Bundle/Inner Pack X Case		24			202	31722526306	-			ST INFORMATION			MHOLESALI	R USE UNL	1.
Pallet		24			203	51722020300	-		Regular Cost			Vendor #:			
							-		Invoice Cost (WAC) (\$)	\$4.00	Whsl. Code	#:		
											÷	Fineline Co			
									As of date:	12/1/2024					
μ									Ц						
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza										
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:															

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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3							
MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? No 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? No	SDS Hazard Classification 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? Is this product regulated for shipment by DOT? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	If yes, indicate which: Hazardous Waste Identification						
d. Packing Group e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
e. Inhalation razard? Is this product regulated for shipment by IATA? No	EFA Hazaldous Waste Cloue.						
(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? No 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 No Limited Distribution Requirement Image: 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	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Phone: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:						
Small Quantity (49 CFR 173.4) Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments						
Is the Product	Comments						
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes						
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes 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						
Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	product in certain states? No No						
Comments:							
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						



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

Version 2021 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: Image: Comparison of the co
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: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?