

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014					Introduction 1	уре:	Post Launch Change		Final Version			Date:	4/13	3/2017
			PRODUCT INFORMATION	ON					SPECIAL HANDL	ING AND STO	RAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale			Ann	lication:	ANDA	a. Temperature – Indic	ata the LICD temper	oturo rongo i	or this prod	unt		
Application Number for ND			<b>)</b> -	90-061	799	ilcution.	711071		ture Range	ature range i			en 20 and 25	5 C (68° – 77° I
		mino rotk)(med device)	<i>y</i> .	00 001				-	=		- COTTLI CHICA T	oom bomo		- 0 (00 11 1
DUNS:	82-667-4775	le:							mperature Range Re	quirement				7
Proprietary Name (If Applical		Name: Finasteri	de Tablets 5MG 30CT	04700 505 00	UPC:	0047005050	~-	_ (wi	rite in)					1
Selling Unit NDC:	31722-525-30 NA		Individual Unit NDC:	31722-525-30		3317225253	U5				0			
UDI			CVX Code:		MVX Code:	NA		<b>╡</b> ┃	oduct to be shipped to				No	_
Description:	Blue, round shaped to	ablets, embossed with '37'	on upper punch and 'H' on lowe	er punch with correspondin	ng dyes			Is this pr	oduct to be shipped to	o customers o	n dry ice?		No	_
Active Ingredient(s):		Finasteride						b. Contact for tempera	ture excursion que	stions:				
UDL for Additional Box book by								Name:			Soma Raju 732-529-04	22		
URL for Additional Product II Address:	Information: www.camberpharma.com 1031 Centennial Avenue				Address 2:			Number			somaraju@heterousa.com			
City:	Piscataway	nue		State:		Zip:	08854	Group E	-maii:		somaraju@r	ieterousa.coi	Ш	
Key Contact:	Customer Service				Email: customerservice@camberpharma.com			c. Special regulations	for product in any c	tatos?			No	
Phone Number:	732-529-0430				Fax: 732-562-8788				eturns requirements t		t?		No	-
Product Therapeutic Classifi								-	7					-
Troduct Therapeutic Glassin	ilication.							d. Store product (unit	of cala) upright?				No	
ADDITIONA	AL PRODUCT INFORM	IATION	1	F	PRODUCT DESCRIF	TION INFORM	IATION		product (unit of sale	a) from light?			No	-
	ALT RODOOT IN ORIN	ATION	1		TRODUCT DECORM	TION IN ORD	ATION	11	product (unit or sale	e) iroin iigiit:				ā
Is the Product								e. Shelf life:					24	Months
a legend device?		No		Size:	30			initiai sn	elf life at launch (if o	airrerent):				Months
reverse numbered? co-licensed?		No No								ORDER INFOR	MATION			
Is the Product		Direct-Ship Only		Strength:	5 mg				•	SKDEK IN OI	KWATION			
Is the Product		Unit of Use						Unit of S	Sale		What is the	NDC selling	unit?	
II is and i reduction				Dosage Form:	Oral solid	tablets		J	Bottle		1 case of 24		,	
II								x	Box/Carton			.g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?		D					Ampule				•	
If Unit Dose NDC, indicate NI	IDC here:			Product Shape	e: Round				Glass		Minimum o	rder quantity	/?	Yes
				Product Color:	: blue				Tube					
Country of Origin		India		1 Todact Colors	. blue				Vial Liquid Sgl					
Is this product covered under	r the Trade Agreements	Act (TAA)?		Product Imprir	nt: 37'/'H'				Vial Liquid Multi		If Yes, how		ich package	type?
		No No		•					Vial Powder Sql			Each		
			J					J	Vial Power Multi			Inner/Cartor	√Pack	
			FOR GENERIC DRUG PROD	ILICTS				_	Other: Write In	1	24	Case		
			TOR GENERIC DROG FROD	0013						_				
				Autho	rized Generic	*If Authorized	Generic, other section		PHAR	RMACY ORDE	R / BILL UN	T		
L Communication of the Communi	AB			Addito	nized Ochene	fields are not		Rec. sell unit to custor						
I. Orange Book Rating: II. Generic Equivalent to Wha		Proscar					-11	Rec. Sell unit to custol	merr	1	KX billing u	nit to pharm Each	acy:	
ii. Generic Equivalent to wha	at Brand?:	FIUSCAI						(Write-in, e.g. 1 Vial)		_		Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT (DS	CSA) INFORMATION				(vviite-iii, e.g. i viai)				Milliliter		
			(	, , , , , , , , , , , , , , , , , , , ,								IVIIIIIIIICI		
Does supplier meet DSCSA	definition of manufac	turer?	Yes	GLN:					ITEM A	ND PACKING	INFORMATI	ON		
Is product exempt from DSC			No		<u> </u>									
If yes, select exemption:									Weight Lbs.	Dimer	sions (US m	nsmts.)	Volume	# Pieces:
Other exemption - Write in:	:								Weight Lbs.	Depth	Height	Width	(Cube)	# Fieces.
Is product repackaged?			No	If Yes, was origina	Il product purchase	d direct		Item:	0.05		3.25	1.75		
Is product sold by manufact			No	from mfr?					****					
Has FDA granted waiver/exc	ception/exemption for	product?	No	If yes, attach docu	umentation from FD	DA.		Box/Carton/Bundle/						
			GTIN PRODUCT INFORMA	TION				Inner Pack:						4
								Case:	2	10.25	4.5	7.25	0.193	24
				leable Unit		Quantity	GTIN-14	Pallet:		-				+
Serialized?	Yes	х	Item	X 2D	Linear		00331722525305	Pallet:						4320
If not, when?	res	1 <del>  ^</del>	Box/Carton/Bundle/Inner Pack	2D 2D	Linear	- '	00331722323303	UPC:	Case:					
Items aggregated?	Yes	x		x x 2D	Linear	24	20331722525309	or c.	Carton:					
aggrogatos:		- <del>-                                  </del>	Pallet	^   ^ 2D	Linear				1					
				2D	Linear			COST	INFORMATION			WHOLESAL	LER USE ON	LY:
				2D	Linear									
				2D	Linear			Regular Cost			Vendor #:			
				2D	Linear			Invoice Cost (WAC) (\$		\$11.50				
				<del>-</del>				Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:		
1	·		·		·			As of date:						
			Attach copy of SAFETY DATA	A SHEET (SDS) or non haz	zard letter, PACKAGE	INSERT, LAB	EL AND PHOTO OF PRO	DDUCT PACKAGING and BA	ARCODE.					



## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):		·
a. Cytotoxic?	SDS Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GIAGGIRIGATORI	
Is the product a CA Prop 65 carcinogen?	Organic Corrosive	
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer	
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard	
a Contact Haranda	A arread Class Identify NEDA Ctarage Levels	
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:	
d. Does this product require special clean-up instructions?  No		
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?	
e. Does the product contain DEHP?	If yes, indicate which:	
Is this product regulated for shipment by DOT or IATA?  No		
(if yes, answer a-e below and provide SDS)		
a. UN/Identification Number		
b. Proper Shipping Name	Hazardous Waste Identification	
c. DOT Hazard Class	EPA Hazardous Waste Code: NA	
d. Packing Group		
e. Inhalation Hazard?		
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS	
Passenger	Is there a REMS on this product?	
Cargo	If Yes, is it managed with a pharmacy registry?	
Passenger & Cargo	Website URL:	
	Website ORL.	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant? No		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		
No (if yes, identify method below)	REMS:	
Limited Quantity	REMS Program Manager Name: Phone:	
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No	
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No No	
Special Permit; DOT-SP	Provider Name:	
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No	
SP#	by Supplier: PCPDP #: No	)
<u></u>	NPI #: No	)
ADD'L STORAGE INFORMATION		
Is the Product	Comments	
Controlled Substance? No		
Controlled by State(s)?	Registry: No	
ARCOS Reportable? No	Registry Program Contact Name: Phone:	
Schedule No. (inc. N for non-narcotic)	Comments	
Controlled Substance Code		
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS	
If yes, indicate which:		
Is it a scheduled listed chemical product?:  No	Contact tel. # if product received damaged: 732-529-0430	
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:	
N c c		
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	URL/Link to returns policy: contact - customerservice@camberpharma.com	
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states?  No	
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments)  No		
Comments:		
MISCELLAI	ANEOUS NOTES and/or Image of Product Barcode:	



## **Standard Pharmaceutical Product Information (Page 3)**

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  Yes  No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern				
c. Fax  d. Phone only  No Phone No.:	Shipping lead time of PO: 24/48 Hours Days				
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No				
Minimum Order Quantity: case pack	Ships for second day receipt:  No				
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt:  Yes				
Contracted 3PL company / contact #: Name: Phone:					
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order: No No	Overnight receipt available: Yes				
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern				
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:				
Comments:	x Tuesday x Wednesday Thursday x Friday				
	Priority Overnight receipt available: Yes				
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No				
Restricted to retail pharmacy only:  Yes	PO Receipt Cut off time:				
Restricted to hospital, clinics, and physician offices only:  No	Order receipt method:  No Phone #:				
Restricted from US territories? (explain in comments)  No	Fax: Yes Fax #: 732-562-8788				
Comments:	EDI: Yes				
	Overnight Fees apply:  Other fees apply:  No				
Other Data Information Demoired to Decree DO					
Other Data Information Required to Process PO:	Return Instructions				
Patient Procedure Date:  Physician Name:	Contact # if product is received damaged:  Is product returnable for credit:  Yes				
Physician/Clinic Phone #	URL/Link to returns policy:				
Physician State License #	Special regulations or returns requirements for this product in certain states?  Yes				
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?				
Physician/Clinic Specialty:	·				
Miscellaneous Notes:					
	ADDITIONAL INFORMATION				
	Is product order for scheduled patient procedure?				
	Is product order for restocking purposes?				