

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introduction Ty	vpe:	Post Launch Change		Final Version			Date:	4/11	/2017
			PRODUCT INFORM	ATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	;*	
Company Name:	Camber Pharmaceuti	cals				Applic	cation:	ANDA	a. Temperature – Indio	ate the USP temper	ature range f	for this produ	ict.		
Application Number for NE	DA/ANDA/BLA (drug);	PMA/510(k)(med devi	ce):	205064	4					ature Range				en 20 and 25	5 C (68° – 77° F
DUNS:	82-667-4775			1					Other Te	emperature Range Re	auirement				
Proprietary Name (If Applica	able) and Established	Name: Aripipi	azole Tablets 15MG 30CT							rite in)					7
Selling Unit NDC:	31722-828-30		Individual Unit NDC:	31	722-828-30	UPC: 3	3317228283	307		,		R			-4
UDI	NA		CVX Code:			MVX Code: 1	NA		Is this p	roduct to be shipped t	to customers	on ice?		No	_
Description:	Light yellow to yellow	round tablets imprinted	d with '97' on upper and 'I' on I	ower					Is this p	roduct to be shipped t	to customers	on dry ice?		No	_
Active Ingredient(s):		Aripiprazole							b. Contact for tempera	ature excursion ques	stions:				,
									Name:			Soma Raju			
URL for Additional Product Address:	Information: 1031 Centennial Ave	www.camberpharma.	com		A	dress 2:			Number			732-529-042	-		
City:	Piscataway	nue			State: N.I		in:	08854	Group E	-maii:		somaraju@	neterousa.co	m	
Key Contact:	Customer Service				State: NJ Zip: 08854 Email: customerservice@camberpharma.com			c. Special regulations	for product in any s	tates?			No		
Phone Number:	732-529-0430					2-562-8788	amborpham			returns requirements		ict?		No	-
Product Therapeutic Classif															-
									d. Store product (unit	of sale) upright?				No	
ADDITION	AL PRODUCT INFORM	ATION			PROD	OUCT DESCRIPTI	ION INFOR	MATION		product (unit of sale	e) from light?	,		No	-
Is the Product									e. Shelf life:		.,			24	Months
a legend device?		No								helf life at launch (if	different) [.]			24	Months
reverse numbered?		No	-	Siz	ze:	30			initial S	ine at launen (ll	amorony.				inonuis
co-licensed?		No	-1	-		45					ORDER INFO	RMATION			
Is the Product		Direct-Ship Only	-1	Str	rength:	15 mg									
Is the Product		Unit of Use	_	Do	sage Form:	Oral Solid ta	ablets		Unit of S	Sale Bottle		What is the 1 box of 48	NDC selling	unit?	
If Unit Dose, is item bar code	lad ta unit daga fan haan	ital accumina?							x	Box/Carton			.g. 1 Box of 1	0 Vials)	
		ital scanning?		Pro	oduct Shape:	Round				Ampule					
If Unit Dose NDC, indicate N	NDC here:		-		oduct Color:	1.1.1.4				Glass Tube		Minimum o	rder quantity	12	Yes
Country of Origin		India		Pro	oduct Color:	Light yellow	to yellow			Vial Liquid Sgl					
Is this product covered under	er the Trade Agreements	s Act (TAA)? No		Pro	oduct Imprint:	'97'/'I'				Vial Liquid Multi Vial Powder Sql		If Yes, how	many of wh Each	ich package	type?
		110	-							Vial Power Multi			Inner/Cartor	n/Pack	
				J						Other: Write In		48	Case		
			FOR GENERIC DRUG PI	RODUCTS								-	•		
					Authorizon	d Canania *	*If Authorizo	d Generic, other section		DUAR		ER / BILL UN	т		
	1.5			, L	Authorized		fields are no		Dec. of the sector						
I. Orange Book Rating:	AB	A LUIS.						applicable .	Rec. sell unit to custo	mer?	-	Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to Wh	hat Brand?:	Abilify							(Write-in, e.g. 1 Vial)				Each Gram		
		DRUG SUP	PLY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION				(write-iii, e.g. i viai)				Milliliter		
				. /											
Does supplier meet DSCSA		urer?	Yes	GLN:						ITEM A	ND PACKING	G INFORMAT	ION		
Is product exempt from DSC If yes, select exemption:	USA?		No	-							Dimo	nsions (US n	emte)	Valum-	
Other exemption - Write in	r.							1		Weight Lbs.	Dime	Height	Width	Volume (Cube)	# Pieces:
Is product repackaged?	••		No	If Yes.	was original pro	oduct purchased	direct	4	Item:	0.4	Depui			(0000)	
Is product sold by manufact			No	from n	nfr?	-				0.1		3.5	1.5		
Has FDA granted waiver/exe	ception/exemption for	product?	No	If yes,	attach documen	ntation from FDA.			Box/Carton/Bundle/						
			GTIN PRODUCT INFOR						Inner Pack:		-				
			GTIN PRODUCT INFOR	Saleable					Case:	4.5	13	4.5	10	0.338	48
			Level	Unit		(Quantity	GTIN-14	Pallet:			-			
Serialized?	Yes	x			X 2D	Linear	Quantity 1	00331722828307							96
If not, when?		1 ^	Box/Carton/Bundle/Inner Pack		2D 2D	Linear			UPC:	Case:					
Items aggregated?	Yes	x		x	x 2D	Linear	48	20331722828301		Carton:					
		-	Pallet		2D	Linear									
					2D	Linear			COST	INFORMATION			WHOLESAL	ER USE ONI	LY:
					2D	Linear									
					2D	Linear			Regular Cost			Vendor #:			
					2D	Linear			Invoice Cost (WAC) (\$		\$45.50	Whsl. Code			
L									Federal Excise Tax Pe	er unit of Sale		Fineline Co	ae:		
									As of date:			-			
			Attach copy of SAFETY DA) or non bazard is							L			
*Discourse data and data	nal information on pag	uo 2	Auach copy of SAFETY DA	A SHEET (SDS)		etter, PACKAGE If e new p. 3 for De									
	mai information on bac	te ∡.			See	e new p. 3 tor De	esignated D	rop anip only.	Signatu	16.					



Standard Pharmaceutical Product Information (Page 2)

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a Cyclosic? ADD performance of Classification because of Classificati	MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION					
a Cyclosic? b CAPPO, 65 Celorisogin or Reproductive Toxonit? b Explosed a CAPPO of Synchronic Based Care Based Care Synchronic Based Care Base	Is this product (check all that apply):						
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d. Oose this product require special observations? No e. Does the product contain DFHP? No e. Does the product contain DFHP? No is the product of the product contain DFHP? No is the product solution DFHP? No is the product solution DFHP? No No Phon	Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard					
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b. Bes the product contain DEHP? No If yes, indicate which: If yes, i							
Is his product stepplante for showner any provide SDS) a UNIdentification Number b Proper Silping Name b Prop	(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?					
(f) Viss, insver = a blow and provide SIS}	e. Does the product contain DEHP? No	If yes, indicate which:					
(f) Viss, insver = a blow and provide SIS}	Is this product regulated for shipment by DOT or IATA2						
b. Proces Shipping Name							
		Hazardovo Wasta Idantification					
d. Packing Group Image: Construct restricted for air shipment? If so, indicate restriction: REMS or REGISTRY RESTRICTIONS is the arady of the air shipment? If so, indicate restriction: REMS or REGISTRY RESTRICTIONS is this are optidate quantity No is this are optidate quantity (40 CFR 172.101): SPR special Prevision (listed thereing product?: No controlled Substance Code No controlled Substance Code No controlled Substance Code No controlled Substance Code No registry Program Contact Name							
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Image: Passenger de argo Is there a REMS On this product light a pharmacy registry? Ves. Is there a REMS On this product light a pharmacy registry? No If Yes, is in anname pollutant? No Is the arrance pollutant? No Consumer Commotity, ORN-D Supplier Manages RNAme: Special Permit: DOT-SP Special Permit: DOT-SP Special Permit: DOT-SP No Statefuld to Substance? No Controlled Substance? No Controlled Substance? No Controlled Substance Code No Listed Chemical (List I or II) No Types, inclasser Code Instruct No Is a scheduled listed inclassen poducut? No <	e. Inhalation Hazard?						
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	WISCELLA						



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if r						
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing					
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier Cut off time: Eastern Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Days Ships regular ground for 3-10 days receipt: Image: Comparison of the compa					
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:	Overnight receipt available:					
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available:					
Class of Trade Restriction:	PO Receipt Cut off time:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply: Image: Content of the content of th					
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?					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					