

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: Post Launch Change Final Version Date: 4/11/2017																
			PRODUCT INFORMAT	ION						SPECIAL HANDL	ING AND STO	ORAGE REQ	UIREMENTS	*		
Company Name:	Camber Pharmaceuti	cale				Applicat	ion:	ANDA	Tomporeture	e - Indicate the USP temper	oturo rongo	for this prod	unt			
Application Number for ND			•	205064		Арріїси	ion.	711071		Temperature Range	ature range			en 20 and 25	5 C (68° – 77° F	
		mayoro(k)(mea aerice)	· ·	200001					_	· -		CONTROLLOG	oom bomo	on to and to	70 (00 11 1	
DUNS:	82-667-4775								۰ ۱	Other Temperature Range Re	quirement				-	
Proprietary Name (If Applical		Name: Aripiprazo	ole Tablets 10MG 30CT						-	(write in)						
Selling Unit NDC:	31722-827-30 NA		Individual Unit NDC:	31722-827-			172282730	0	- 11 .	and the same transfer and the same transfer				NI.		
UDI			CVX Code:		IVIV	/X Code: NA			= 1	s this product to be shipped to				No	_	
Description:	Light pink to pink mod	ified rectangular tablets in	nprinted with '96' on upper an	d 'I' on lower					l:	s this product to be shipped to	o customers o	on dry ice?		No	_	
		1														
Active Ingredient(s):		Aripiprazole								temperature excursion que	stions:					
UDI Con A LISS and Box box b			-							Name:		Soma Raju 732-529-04	22			
URL for Additional Product In Address:					Address 2:					Number: Group E-mail:			somaraju@heterousa.com			
City:							Group E-mail: somaraju@neterousa.com									
Key Contact:	Piscataway Customer Service State: NJ Zip: Email: customerservice@camberpharm					c. Special regulations for product in any states?										
Phone Number:	Customer Service					Special requirements for this product?										
Product Therapeutic Classifi															-	
Troduct Therapeutic Glassin	ication.								d Store produc	ct (unit of sale) upright?				No		
ADDITIONA	AL PRODUCT INFORM	ATION	Ī		PRODUC	T DESCRIPTIO	N INFORM	ATION		ct (unit of sale) uprignt? Protect product (unit of sale) from light?	,		No	_	
	ALT RODOOT IN ORIN	ATION			TRODUC	or become no	IV IIVI OIVIII	411014	-	rotect product (unit or sale	e) iroin iigiit:				ā	
Is the Product									e. Shelf life:					24	Months	
a legend device?		No No		Size:		30			"	nitial shelf life at launch (if o	airrerent):				Months	
reverse numbered? co-licensed?		No No									ORDER INFO	PMATION				
Is the Product		Direct-Ship Only		Strength:		10 mg					JRDER IN O	KWATION				
Is the Product		Unit of Use							ill ,	Unit of Sale		What is the	NDC selling	unit?		
II is the resulting				Dosage Fo	rm:	Oral Solid table	et		III ř	Bottle		Box of 12 bo				
II									'll	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					111 F	Ampule		, , , ,	3	,		
If Unit Dose NDC, indicate NI	DC here:			Product Sh	nape:	rectangular				Glass		Minimum o	rder quantity	<i>i</i> ?	Yes	
				Product Co	olor:	Light pink to pi	nk			Tube						
Country of Origin		India		1100000100	,,,,,,	Light pink to pi	i iix			Vial Liquid Sgl						
Is this product covered under the Trade Agreements Act (TAA)?					L	Vial Liquid Multi		If Yes, how		ch package	type?					
	9	No No			•				!	Vial Powder Sql			Each	-		
									JI ⊨	Vial Power Multi		12	Inner/Cartor	/Pack		
			FOR GENERIC DRUG PRO	DUCTS						Other: Write In	1		Case			
			TOR GENERIC DROG FIRE	00013												
				Δ	uthorized Ge	neric *If	Δuthorized	Generic, other section		PHAR	RMACY ORDE	R / BILL UN	T			
L Communication of the Communi	AB				attionized Oc		ds are not a		Dan call switte							
I. Orange Book Rating:		Abilify						-11	Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Abilify								(Write-in, e.g. 1	I \/ial\			Each Gram				
		DRUG SUPPI	Y CHAIN SECURITY ACT (E	SCSA) INFORMATION					(vviite-iii, e.g. i	i viaij			Milliliter			
			(,								L	IVIIIIIIIICI			
Does supplier meet DSCSA	definition of manufac	turer?	Yes	GLN:						ITEM A	ND PACKING	INFORMATI	ON			
Is product exempt from DSC			No													
If yes, select exemption:										Weight Lbs.	Dime	nsions (US m	nsmts.)	Volume	# Pieces:	
Other exemption - Write in:	:									Weight Lbs.	Depth	Height	Width	(Cube)	# Fieces.	
Is product repackaged?			No	If Yes, was orig	jinal produc	ct purchased di	rect		Item:	0.1		3.125	1.5			
Is product sold by manufact			No	from mfr?					11-							
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes, attach d	ocumentati	ion from FDA.			Box/Carton/Bu	ndle/	6.5	3.125	4.75	0.056	12	
			GTIN PRODUCT INFORM	ATION					Inner Pack:							
									Case:	16	15.25	9.75	13.75	1.183	96	
			Level	Saleable Unit		O	antity (GTIN-14	Pallet:							
Serialized?	Yes	х	Item	X 2D				00331722827300	۱ ^{۲ هااو ز}						4800	
If not, when?	163	1 ×	Box/Carton/Bundle/Inner Pack	x x 2D				10331722827307	UPC:	Case:			1	l	1	
Items aggregated?	Yes	x	Case	x 2D				30331722827301	11110.0.	Carton:						
		·	Pallet	2D		Linear	È		111	1						
				2D		Linear				COST INFORMATION			WHOLESAL	ER USE ON	LY:	
				2D		Linear										
				2D		Linear			Regular Cost			Vendor #:				
				2D		Linear			Invoice Cost (V		\$45.50					
										Tax Per Unit of Sale		Fineline Co	de:			
	·				·				As of date:							
			Attach copy of SAFETY DA	TA SHEET (SDS) or non	hazard letter	r, PACKAGE INS	SERT, LABI	EL AND PHOTO OF P	ODUCT PACKAGING	and BARCODE.						
L	nal information on pag	10.2			See ne	ew p. 3 for Desi	anated Dra	on Shin Only	5	Signature:						



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 Glassification	
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 Homand?	A areaal Class Identify NEDA Stayana Lavaly	
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:	
d. Does this product require special clean-up instructions? No	1.4. 1.4. 1100111	
(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: N/A	
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? Yes	
Cargo	If Yes, is it managed with a pharmacy registry?	
	Website URL:	
Passenger & Cargo	Website ORL.	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant? No	None	
Is this product shipped utilizing an authorized DOT exception or Special Permit?		
No (if yes, identify method below)	REMS: Yes	
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	
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 None	
Controlled Substance? No		
Controlled by State(s)?	Registry: No	<u></u>
ARCOS Reportable?	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:	
No. 10 at 10		
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	URL/Link to returns policy: contact - customerservice@ca	'
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: No	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments) No		
Comments:		
MISCELLAI	NEOUS 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?					