

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

© August 2014					Int	troduction Type:	Pos	st Launch Change		Final Version			Date:	4/11	/2017
			PRODUCT INFORM	ATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS'		
Company Name: Application Number for ND	Camber Pharmaceuti		vice):	205064		Application	:	ANDA	a. Temperature – Indio Tempera	ate the USP temper ture Range	rature range			en 20 and 25	C (68° – 77° ł
DUNS:	82-667-4775	i ili to ro(k)(iliou uo							-	mperature Range Re	quiromont				- (
Proprietary Name (If Applical		Name: Aripi	prazole Tablets 2MG 30CT							ite in)	quirement				7
Selling Unit NDC:	31722-819-30		Individual Unit NDC:			UPC: 33172	2819305		(	,					_
UDI	NA		CVX Code:		M۱	/X Code: NA			Is this pr	oduct to be shipped t	o customers	on ice?		No	_
Description: Light green to green modified rectangular tablets imprinted with '94' on upper and 'I' on lower							Is this product to be shipped to customers on dry ice? <u>No</u>								
Active Ingredient(s): Aripiprazole						b. Contact for temperature excursion questions: Name: Soma Raju									
URL for Additional Product I	Information:	www.camberpharma	a.com						Number	:		732-529-04	23		
Address:	1031 Centennial Avenue Address 2:						Group E-mail: somaraju@heterousa.com								
City:	Piscataway     State:     NJ     Zip:     08854														
Key Contact: Phone Number:	Customer Service     Email:     customerservice@camberpharma.com       732-529-0430     Fax:     732-562-8788				om	c. Special regulations for product in any states? No Special returns requirements for this product? No									
Product Therapeutic Classifi															
rioudor morapouto otacom									d. Store product (unit	of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM	IATION			PRODUC	CT DESCRIPTION IN	NFORMAT	TION	Protect product (unit of sale) from light? No						
Is the Product															Months
a legend device?		No		Size:		30			Initial sh	elf life at launch (if	different):				Months
reverse numbered?		No		0120.								DIATION			
co-licensed? Is the Product		No Direct-Ship Only	—	Strengt	h:	2 mg				(	order info	RMATION			
Is the Product		Unit of Use	—	_	_				Unit of S	ale		What is the	NDC selling	unit?	
			—	Dosage	Form:	Oral Solid tablet				Bottle		1 box of 12			
If Unit Dose, is item bar code	ed to unit dose for hose	ital scanning?							x	Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
				Produc	Shape:	Rectangular				Ampule				•	N.
If Unit Dose NDC, indicate N	IDC here:									Glass Tube		Minimum o	rder quantity	7	Yes
Country of Origin		India		Produc	Color:	Light green to gree	en			Vial Liquid Sql					
Is this product covered under	r the Trade Agreements	Act (TAA)?	_	Produc	Imprint:	94'/'l'				Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
io the product covered ander		No No	_			, .				Vial Powder Sql		10	Each		
									J	Vial Power Multi Other: Write In		12	Inner/Carton Case	Pack	
			FOR GENERIC DRUG P	RODUCTS						Other. White hi	1		Case		
Authorized Generic *If Authorized Generic, other section							PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	AB					fields a	are not ap	plicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What	at Brand?:	Abilify							Each						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g. 1 Vial)				Gram Milliliter				
				()									IVIIIIIIII		
Does supplier meet DSCSA		turer?	Yes	GLN:					ITEM AND PACKING INFORMATION						
Is product exempt from DSC	CSA?		No	_											
If yes, select exemption: Other exemption - Write in:										Weight Lbs.	Dime	nsions (US m Height	width	Volume (Cube)	# Pieces:
Is product repackaged?	•		No	If Yes, was	original produ	ct purchased direc	t		Item:		Deptil			(ouse)	
Is product sold by manufact	turer's exclusive distr	ibutor?	No	from mfr?			_			0.1		3.125	1.5		
Has FDA granted waiver/exc	ception/exemption for	product?	No	If yes, attac	h documentat	ion from FDA.			Box/Carton/Bundle/ Inner Pack:	1.1	6.5	3.75	4.875	0.69	12
			GTIN PRODUCT INFOR						Case:						
				Saleable						16.1	15.5	9.5	14.625	1.246	96
			Level	Unit		Quanti		IN-14	Pallet:						4800
Serialized?	Yes	×		x	2D	Linear 1		331722819305			_				
If not, when? Items aggregated?	Yes	x		x x x	2D 2D	Linear 12 Linear 96		331722819302 331722819306	UPC:	Case: Carton:					
items aggregated	163		Pallet		2D 2D	Linear		331722019300		Carton.					
2D Linear						COST	INFORMATION			WHOLESAL	ER USE ONI	LY:			
					2D	Linear									
2D Linear 2D Lin						Regular Cost	<b>`</b>	A 1 - C -	Vendor #:	4.					
							Invoice Cost (WAC) (\$ Federal Excise Tax Pe		\$45.50	Whsl. Code Fineline Co					
									As of date:			1 110/1110 00			
	Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.														
*Please provide any addition	nal information on page	ge 2.			See n	ew p. 3 for Designa	ated Drop	Ship Only.	Signatu	re:					



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

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	SDS Hazard Classification					
	NO	SDS nazard Glassification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	No	Organic Corrosive					
Is the product a CA Prop 65 reproductive toxicant?		Inorganic Oxidizer					
Does the product label bear a CA Prop 65 warning?		Steroid/Androgen Contact Hazard					
c. Contact Hazard?	No	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?	No	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	ŀ	Is there a REMS on this product? Yes					
Cargo							
Passenger & Cargo		Website URL: N/A					
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					
		NPI#: No					
ADD'L STORAGE INFORMATION							
Is the Product		Comments None					
Controlled Substance?	No						
Controlled by State(s)?	No	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: Yes					
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:	No	If so, which states? Other requirements? Comments?					
Restricted from US territories? (explain in comments)	No						
Comments:							
Comments.							
<u>M</u>	ISCELLAN	EOUS 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:   Autofax   Yes     b. Autofax   No   Fax Number:     c. Fax   Yes   Fax Number:     d. Phone only   No   Phone No.:     e. Supplier Web Site only   No   Site Address:     Minimum Order Quantity:   case pack   732-529-0430 x466 x465 x467 x470     Contracted 3PL company / contact #:   Name:   Phone:	Purchase order daily receipt cut off time by supplier     Cut off time:   2:30PM   Eastern     Shipping lead time of PO:   24/48   Hours   Days     Ships same day for next day receipt:   No   No     Ships for second day receipt:   No   No     Ships regular ground for 3-10 days receipt:   Yes						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:   No     Drop Ship service fee billed with each order:   No     Drop Ship miscellaneous fees billed:   No     Comments:   Image: No     Comments:   Image: No     Class of Trade Restriction:     No     Restricted to retail pharmacy, hospitals, clinics and physician offices     No   Yes     Restricted to hospital, clinics, and physician offices only:   No     Restricted from US territories? (explain in comments)   No	Overnight receipt available:   Yes     PO Receipt cut off time:   2:30PM   Eastern     Days of week overnight is available:   X   Monday     X   Tuesday   Wednesday     X   Thursday   Friday     Priority Overnight receipt available:   Yes     PO Receipt Cut off time:   2:30PM EST     Saturday Overnight receipt available:   No     PO Receipt Cut off time:   No     Order receipt method:   Phone:   No     Fax:   Yes   Fax #:						
Comments:	rax. res rax #. res   EDI: Yes   Overnight Fees apply: Yes   Other fees apply: No						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:	Contact # if product is received damaged:   732-529-0430     Is product returnable for credit:   Yes     URL/Link to returns policy:						
	ADDITIONAL INFORMATION						