

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

						Introduction Ty	pe: New Item			x Final Version			Date:	3/18/	/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA a.							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN			e):	21	6150					Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applica	,.	, , , , , , , , , , , , , , , , , , ,	<u>, </u>												
DUNS:	11-856-3719									Other Temperature Range F	tequirement	Excursions p	ermitted bety	veen 15°C to	30°C (59°F
Proprietary Name (If Applicable)	and Established N	ame: Aripipr	azole Oral Solution, 1 mg/m	L						(write in)	•	to 86°F)			`
Selling Unit NDC:	31722-684-15		Unit of Use NDC:		31722-684-15	UPC:	331722684156			Notes		Opened bottles of a			
UDI			CVX Code:			MVX Code:						after opening, but r	ot beyond the exp	ration date on the b	bottle.
Description:	Aripiprazole Oral	Solution, 1 mg/mL								Is this product to be shipped	to customers on ic	e?		No	1
			ottles along with a calibrat	ed oral dosing	cup.**					Is this product to be shipped				No	
Active Ingredient(s): Aripiprazole, USP															
									b. Contact for	temperature excursion que	stions:				
URL for Additional Product Inforr	mation:	www.camberpharma	.com							Name:		Soma Raju			
Address:		Ave (and) 800 Center	nial Ave, Suite 1			Address 2:				Number:		732-529-042			
City:	,				Zip : 08854		Group E-mail: somaraju@heterousa.com			1					
Key Contact:	1-866-827-3647	e			Email:	732-562-8788	camberpharma.com				-1-10			NI.	1
Phone Number:		At a last Astlessorts	··-		Fax:	/32-302-0/00				ulations for product in any				No	
Product Therapeutic Classification	on:	Atypical Antipsycho	tic							Special returns requirement	s for this product?			No]
	ADDIT	IONAL PRODUCT IN	FORMATION			DRODUCT DE	ESCRIPTION INFORMATION	ION						NI.	1
	ADDIT	IONAL PRODUCT IN				PRODUCT DE	SCRIPTION INFORMATION	ION	a. Store produ	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only					Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	150 mL		e. Shelf life:					24	Months
if yes, enter class #		Nie	Orphan Drug Status				4 / 1			Initial shelf life at launch (i	f different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	1 mg/mL				ORDER INFORM	ATION			
component parts			i DA Appiovai Status				Oral Solution				ORDER IN ORM	ATION			
reverse numbered?		No				Dosage Form:	Oral Columbia			Unit of Sale		What is the I	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 15			
latex-free?		Yes		ol, Sugar		Product Shape	N/A			Box/Carton		(Write-in, e.g	. 1 Box of 10	Vials)	
preservative-free?		No	Alcono	oi, Sugar		Product Snape	#:			Ampule					
correctional institution block?		No				Product Color	Clear, colorless to li	light		Glass		Minimum or	der quantity	?	Yes
opioid?		No					yellow			Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri	nt: N/A			Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		to this and door account of	and an the		·				Vial Liquid Multi		If Yes, how i		ch package t	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered un Trade Agreements Act (No					Vial Powder Sql Vial Power Multi			Each Inner/Carton	/De els	
ii Onit Dose, indicate NDC here:			Trade Agreements Act (IAA)!	INO					Other: Write In			mner/Carton Case	Pack	
			EOR CENERIC DRUG DR	ODUCTS						Other. Write III			Case		
		FOR GENERIC DRUG PRODUCTS													
DIADMASY ORDER AND THE															
					Au	thorized Generic *	If Authorized Generic other	ner		PH	ARMACY ORDER	BILL UNIT			
L Orange Bask Basings	ΔΔ			_	Au		'If Authorized Generic, other		Pac sall unit t		ARMACY ORDER		it to whome		
I. Orange Book Rating:	AA	Δhilify			Au		If Authorized Generic, other section fields are not applicated.		Rec. sell unit t			Rx billing ur		ıcy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Abilify			Au					to customer?		Rx billing ur	Each	су:	
			Y CHAIN SECURITY ACT ((DSCSA) INFO					Rec. sell unit to	to customer?		Rx billing ur		icy:	
			Y CHAIN SECURITY ACT ((DSCSA) INFO						to customer?		Rx billing ur	Each Gram	icy:	
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	Yes	(DSCSA) INFO						to customer?		Rx billing ur	Each Gram Milliliter	icy:	
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II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	Yes	(DSCSA) INFO	RMATION					to customer? 1 Vial) ITEM	AND PACKING IN	Rx billing ur	Each Gram Milliliter	volume	Saleable #
II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA?	and?:	DRUG SUPPL	Yes	(DSCSA) INFO	RMATION GLN:					to customer?	AND PACKING IN	Rx billing ur	Each Gram Milliliter		Saleable # Pieces
II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: iition of manufactu	DRUG SUPPL	Yes No	(DSCSA) INFO	GLN: GCP: If yes, was or	0331722000000 iginal product purch	section fields are not applic			to customer? 1 Vial) ITEM Weight Lbs.	AND PACKING IN Dimensio Depth	Rx billing ur FORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
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Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATE	ERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic?	No	SI	S Hazard Classification				
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 No No	x Organic Inorganic Steroid/Androgen	Corrosive Oxidizer 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?	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	No				
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
c. DOT Hazard Class d. Packing Group		Hazardous Waste Identification					
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics			
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No	REMS o	r 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? If Yes, is it managed with a pharmacy registry? Website URL:	No				
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No				
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 Small Quantity (49 CFR 173.4)		REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:	No	Phone: DEA #: NCPDP#: NPI #:			
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments					
SP#		Registry: Registry Program Contact Name:	No	Phone:			
ADD'L STORAGE INFORMATION Is the Product		Comments					
Controlled Substance? Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. Controlled Substance Code Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	No No	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:	1-866-827-3647 Yes				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	, ,	rvice@camberpharma.com				
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only:	No No	Special regulations or returns requirements for this product in certain states?	No				
Restricted from US territories? (explain in comments) Comments:	No	If so, which states? Other requirements? Comments?					
MISC	CELLANEO	US 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 S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed 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: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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? Is product order for restocking purposes?