

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

Version 2021						Introduction Type	e: Post Launch Change		x Final Version			Date:	6/23/	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	: ANDA	a. Temperature -	Indicate the USP tempe	rature range for the	nis product.			
				5064	- 11		•	mperature Range	Controlled Room -		and 25 C (68	° – 77° F)		
Medical Device Class, if applicab		( //	•						,					
DUNS:	11-856-3719							Oti	her Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Aripip	orazole Tablets 2 mg						(write in)	·				
Selling Unit NDC:	31722-819-30		Unit of Use NDC:		31722-819-30		1722819305	No	otes					
UDI			CVX Code:			MVX Code:								
Description:	Aripiprazole Table	ets 2 ma						ls t	this product to be shipped	I to customers on id	e?		No	1
•		Ü							this product to be shipped				No	1
Active Ingredient(s):		Aripiprazole, USP												
							b. Contact for ten	nperature excursion que	estions:					
URL for Additional Product Inform		www.camberpharn	na.com						ime:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:			ımber:		732-529-042			
City:	Piscataway				State:		ip: 08854	Group E-mail:			somaraju@h	omaraju@heterousa.com		
Key Contact:	1-866-827-3647				customerservice@ca	amberpharma.com	c. Special regulations for product in any states?				NI.	1		
Phone Number:		At a lead and a cost	-11-		Fax:	732-562-8788							No	-
Product Therapeutic Classification	1:	Atypical antipsych	otic					Sp	ecial returns requirement	s for this product?			No	_
	ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?											7		
	ADDITI	ONAL PRODUCT II				PRODUCT DES	SCRIPTION INFORMATION	-	(unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship (	Only				otect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct	e. Shelf life:					24	Months
if yes, enter class #		1	Orphan Drug Status					Ini	tial shelf life at launch (i	f different):				Months
a product kit?		No	EDA 4			Strength:	2 mg			ORDER INFORM	IATION			
if yes, list NDCs of			FDA Approval Status				Tablet			ORDER INFORM	IATION			
component parts reverse numbered?		No				Dosage Form:	lablet	He	nit of Sale		What is the I	NDC selling	unit?	
co-licensed?		No	Allergens Present					J	x Bottle		1 Bottle of 30		<b></b>	
latex-free?		Yes					Modified rectangular,		Box/Carton		(Write-in, e.g		) Vials)	
preservative-free?		Yes	La	ctose		Product Shape:	bevel edged, biconvex		Ampule		(	,	,	
correctional institution block?		No				Product Color:	Plain to mottled light		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:	green to green		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	Debossed with 'I' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					r roduct imprint	and '94' on the other side		Vial Liquid Multi		If Yes, how I		ch package t	type?
hospital scanning?			Is this product covered u						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ΓAA)?	No				Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
									BU	ARMACY ORDER	/ DULL LINET			
				_	Auti		Authorized Generic, other action fields are not applicable			ARMACY ORDER				
	AB					56	ction neids are not applicable	Rec. sell unit to c	customer?		Rx billing ur		acy:	
II. Generic Equivalent to What Brai	nd?:	Abilify										Each		
		DRIIG SUBB	LY CHAIN SECURITY ACT	DSCSA) INFO	2MATION .			(Write-in, e.g. 1 V	ial)			Gram Milliliter		
		DRUG SUPP	LT CHAIN SECURITY ACT	DSCSA) INFO	RWATION							Milliter		
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes	_	GLN:	0331722498975			ITEM	AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?	non or manaractar		No	_	OLIV.	0001122400010				7				
If ves. select exemption:			·		GCP:					Dimensi	ons (US msm	te \	Volume	Saleable #
If yes, select exemption: Other exemption - Write in:					GUP:				Weight Lbs.	Depth	Width	ts.) Height	(Cube)	Pieces
Is product repackaged?			No		If you was orig	ginal product purcha	bos	Item/Each:		i i				
Is product sold by manufacturer's	exclusive distribu	ıtor?	Yes	_	direct from mf		seu	nem/Lucii.	0.08	1.58	1.58	3.13	7.81	1
Has FDA granted waiver/exception			No	+		manufacturer for re	epackaged product	Box/Carton/Bund	lle/					
								Inner Pack:						
If yes, attach documentation from	n FDA.							Case:				4.25	552.50	48
If yes, attach documentation from	n FDA.										10		552.50	40
If yes, attach documentation from	n FDA.	GT	TIN AND HIBCC PRODUCT I	NFORMATION				ouse.	4.3	13	10	4.23		
				NFORMATION				Pallet:	4.3	13	10	4.20		
Saleable Unit of Measure		Saleable Quantity	TIN AND HIBCC PRODUCT I	NFORMATION	GTIN		Unit of Use GTIN-14		4.3	13	10	4.23		
Saleable Unit of Measure				NFORMATION		-14 1722819305	Unit of Use GTIN-14 00331722819305			13				V
Saleable Unit of Measure  X Item/Each Box/Carton/Bundle/Inner Pack		Saleable Quantity		NFORMATION	0033	1722819305			4.3  COST INFORMATION	13			ER USE ONL	Y:
Saleable Unit of Measure  X   ttern/Each   Box/Carton/Bundle/Inner Pack   X   Case		Saleable Quantity		NFORMATION	0033			Pallet:		13	\		ER USE ONL	.Y:
Saleable Unit of Measure  X Item/Each Box/Carton/Bundle/Inner Pack		Saleable Quantity		NFORMATION	0033	1722819305		Pallet:	COST INFORMATION		Vendor #:	VHOLESALI	ER USE ONL	lY:
Saleable Unit of Measure  X   ttern/Each   Box/Carton/Bundle/Inner Pack   X   Case		Saleable Quantity		NFORMATION	0033	1722819305		Pallet:	COST INFORMATION		Vendor #: Whsl. Code	VHOLESALI	ER USE ONL	.Y:
Saleable Unit of Measure  X   ttern/Each   Box/Carton/Bundle/Inner Pack   X   Case		Saleable Quantity		NFORMATION	0033	1722819305		Pallet:  Regular Cost Invoice Cost (WA	COST INFORMATION		Vendor #:	VHOLESALI	ER USE ONL	.Y:
Saleable Unit of Measure  X   ttern/Each   Box/Carton/Bundle/Inner Pack   X   Case		Saleable Quantity		NFORMATION	0033	1722819305		Pallet:	COST INFORMATION		Vendor #: Whsl. Code	VHOLESALI	ER USE ONL	.Y:
Saleable Unit of Measure  X   ttern/Each   Box/Carton/Bundle/Inner Pack   X   Case		Saleable Quantity		NFORMATION	0033	1722819305		Pallet:  Regular Cost Invoice Cost (WA	COST INFORMATION		Vendor #: Whsl. Code	VHOLESALI	ER USE ONL	Y:
Saleable Unit of Measure  X   ttern/Each   Box/Carton/Bundle/Inner Pack   X   Case		Saleable Quantity	HIBCC		2033	1722819305 1722819309		Pallet:  Regular Cost Invoice Cost (WA As of date:	COST INFORMATION  AC) (\$)  4/1/2021		Vendor #: Whsl. Code	VHOLESALI	ER USE ONL	Y:



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#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic?  No	SDS 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?  No  Does the product label bear a CA Prop 65 warning?  No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen 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?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:					
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	Is the product a NIOSH hazardous drug?  If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS					
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:					
Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
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); SP#	Comments					
ADD'L STORAGE INFORMATION	Registry:  Registry Program Contact Name:  Comments  No  Phone:					
Is the Product						
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No.  No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  I-866-827-3647  Is product returnable for credit:  Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	URL/Link to returns policy:  contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments)  No  Comments:	If so, which states? Other requirements? Comments?					
MISCELLANE	DUS NOTES and/or Image of Product Barcode:					



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#### 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?