



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

Version 2021 Introduction Type:  New Item  Final Version Date: 3/18/2024

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216150  
 Medical Device Class, if applicable:  
 DUNS: 11-856-3719  
 Proprietary Name (If Applicable) and Established Name: Aripiprazole Oral Solution, 1 mg/mL  
 Selling Unit NDC: 31722-684-15 Unit of Use NDC: 31722-684-15 UPC: 331722684156  
 UDI CVX Code: MVX Code:  
 Description: Aripiprazole Oral Solution, 1 mg/mL  
 \*\*Note - supplied in child-resistant bottles along with a calibrated oral dosing cup.\*\*  
 Active Ingredient(s): Aripiprazole, USP  
 URL for Additional Product Information: www.camberpharma.com  
 Address: 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 Address 2:  
 City: Piscataway State: NJ Zip: 08854  
 Key Contact: Customer Service Email: customerservice@camberpharma.com  
 Phone Number: 1-866-827-3647 Fax: 732-562-8788  
 Product Therapeutic Classification: Atypical Antipsychotic

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)  
 Other Temperature Range Requirement (write in): Excursions permitted between 15°C to 30°C (59°F to 86°F)  
 Notes: Opened bottles of aripiprazole oral solution can be used for up to 6 months after opening, but not beyond the expiration date on the bottle.  
 Is this product to be shipped to customers on ice?  No  
 Is this product to be shipped to customers on dry ice?  No  
**b. Contact for temperature excursion questions:**  
 Name: Soma Raju  
 Number: 732-529-0423  
 Group E-mail: somaraju@heterousa.com  
**c. Special regulations for product in any states?**  No  
 Special returns requirements for this product?  No  
**d. Store product (unit of sale) upright?**  No  
 Protect product (unit of sale) from light?  No  
**e. Shelf life:**  24 Months  
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class # a product kit? if yes, list NDCs of component parts reverse numbered? co-licensed? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid?	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No	Is the Product... Direct-Ship Only Is the Product... Unit of Use Orphan Drug Status FDA Approval Status Allergens Present Alcohol, Sugar Country of Origin India	Size: 150 mL Strength: 1 mg/mL Dosage Form: Oral Solution Product Shape: N/A Product Color: Clear, colorless to light yellow Product Imprint: N/A
If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:	<input type="checkbox"/> <input type="checkbox"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?	Minimum order quantity?	If Yes, how many of which package type?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 150 mL Oral Solution (Write-in, e.g. 1 Box of 10 Vials)	<input type="checkbox"/> Yes	<input type="checkbox"/> 12 Each <input type="checkbox"/> Inner/ Carton/Pack <input type="checkbox"/> Case
<input type="checkbox"/> Box/ Carton			
<input type="checkbox"/> Ampule			
<input type="checkbox"/> Glass			
<input type="checkbox"/> Tube			
<input type="checkbox"/> Vial Liquid Sgl			
<input type="checkbox"/> Vial Liquid Multi			
<input type="checkbox"/> Vial Powder Sgl			
<input type="checkbox"/> Vial Power Multi			
<input type="checkbox"/> Other: Write In			

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating: AA  Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?: Abilify

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer? (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy: Each, Gram, Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes  
 Is product exempt from DSCSA?  No  
 If yes, select exemption: Other exemption - Write in:  
 Is product repackaged?  No  
 Is product sold by manufacturer's exclusive distributor?  Yes  
 Has FDA granted waiver/exception/exemption for product?  No  
 If yes, attach documentation from FDA.  
 GLN: 0331722000000  
 GCP:  
 If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.58	2.26	2.26	5.55	28.35	1
Case:	7.75	9.5	7.5	6	427.50	12
Pallet:						

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722684156	00331722684156
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	12		20331722684150	
<input type="checkbox"/> Pallet				

**COST INFORMATION** **WHOLESALE USE ONLY:**

Regular Cost  
 Invoice Cost (WAC) (\$) \$150.00  
 As of date:  
 Vendor #: Whsl. Code #: Finline Code:



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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
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - Is the product a CA Prop 65 carcinogen?  No
  - Is the product a CA Prop 65 reproductive toxicant?  No
  - Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger  No
- Cargo
- Passenger & Cargo

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)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes
- Controlled by State(s)?  No  Yes
- ARCOS Reportable?  No  Yes
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II)  No  Yes
- If yes, indicate which:
- Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No

Is the product a NIOSH hazardous drug? If yes, indicate which:  No

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  Yes

If Yes, is it managed with a pharmacy registry? Website URL:

Med Guide Required  No  Yes

Limited Distribution Requirement  No  Yes

Comments / Details: (For example, iPledge program?)

REMS:  No  Yes

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:  No  Yes

Wholesale distributor support:

Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  NCPDP#:

Comments:

Registry:  No  Yes

Registry Program Contact Name:  Phone:

Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647

Is product returnable for credit:  Yes  No

URL/Link to returns policy:  contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No  Yes

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

