



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Pre-Launch Change Post-Launch Change Final Version

Date: 10/15/19

PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A090768
 DUNS: 022490515
 Proprietary Name (If Applicable) and Established Name: Donepezil Tablets
 Selling Unit NDC: 59746-0330-30 Individual Unit NDC: _____ UPC: 3-59746-330-30
 UDI: _____ CVX Code: _____ MVX Code: _____
 Description: Donepezil 10mg Tablets 30ct
 Active Ingredient(s): Donepezil
 URL for Additional Product Information: www.cadista.com
 Address: 207 Kiley Drive Salisbury, MD 21801
 Key Contact: Jackie Emershaw Email: Jackie.Emershaw@cadista.com
 Phone Number: (410) 912-3722 Fax: (215) 443-9646
 Product Therapeutic Classification: _____

SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77°)
 Other Temperature Range Requirement (write in): _____
 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: Customer Support
 Number: (800) 313-4623
 Group E-mail: _____
 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): 24 Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device? Yes
 reverse numbered? No
 co-licensed? No
 Is the Product... Direct-Ship Only
 Is the Product... _____
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose NDC, indicate NDC here: _____
 Country of Origin: _____
 Is this product covered under the Trade Agreements Act (TAA)?

PRODUCT DESCRIPTION INFORMATION

Size: 30ct
 Strength: 10mg
 Dosage Form: TAB
 Product Shape: Round
 Product Color: Off-White
 Product Imprint: J | 10

ORDER INFORMATION

Unit of Sale: Bottle, Box/Carton, Ampule, Glass, Tube, Vial Liquid Sgl, Vial Liquid Multi, Vial Powder Sgl, Vial Power Multi, Other: Write In _____
 What is the NDC selling unit? 1 case of 48 bottles (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity? Yes
 If Yes, how many of which package type?
 48 Each, Inner/Carton/Pack, Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Aricept®

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 No
 Is product exempt from DSCSA? Yes No
 If yes, select exemption: _____
 Other exemption - Write in: _____
 Is product repackaged? Yes No
 Is product sold by manufacturer's exclusive distributor? Yes No
 Has FDA granted waiver/exception/exemption for product? Yes No
 GLN: 8902805000006
 If Yes, was original product purchased direct from mfr? Yes No
 If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.1	1.69	3.19	1.69	9.11	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	4.95	14.75	5	11.13	820.84	48
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Saleable Unit	Unit		
<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	Item	1	00359746330309
			<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack		
			<input checked="" type="checkbox"/>	Case	48	40359746330307
			<input checked="" type="checkbox"/>	Pallet		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		

COST INFORMATION

Regular Cost: _____ Vendor #: _____
 Invoice Cost (WAC) (\$): \$2.18 Whsl. Code #: _____
 Federal Excise Tax Per Unit of Sale: _____
 As of date: _____

WHOLESALE USE ONLY:

Fineline Code: _____
 Signature: _____

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? No
 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? No
 (If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

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

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

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

Passenger

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

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

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 restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

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

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

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

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:
 Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments:

Registry:

Registry Program Contact Name: Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

