

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

						Introduction Type	Post Launch Change		x Final Version			Date:	7/12/	2021
			PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 090768										n – between 20 and 25 C (68° – 77° F)				
Medical Device Class, if applical		, , ,	•						,					
DUNS:	022490515							Oth	her Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established N	ame: Donepe	zil HCl Tablets					1	(write in)					
Selling Unit NDC:	59746-330-90		Unit of Use NDC:			UPC: 3-5	9746-330-90-3	No	ites					
UDI			CVX Code:			MVX Code:								
Description:	Donepezil Hydrod	hloride 10mg 90ct Tab	olet					ls t	this product to be shipped	to customers on i	ce?		No	
2000	,,								this product to be shipped				No	
Active Ingredient(s):		Donepezil Hydrochlo	ride								•			
								b. Contact for ten	nperature excursion que	estions:				
URL for Additional Product Inform		www.cadista.con	n/products/full-product	t-list				Na	ime:		Customer Se	ervice		
Address:	207 Kiley Drive					Address 2:		Nu	ımber:		(800) 313-46	23		
City:	Salisbury				State:		p: 21801	Gre	oup E-mail:		customer.	service@ca	<u>dista.com</u>	
Key Contact:	Jackie Emershaw	<u> </u>			Email:	Jackie.Emershaw@	<u> Pjubl.com</u>							
Phone Number:	(410) 912-3722	la			Fax:	(215) - 443 - 9646			tions for product in any				No	
Product Therapeutic Classificatio	on:	Dementia Treatment						Sp	ecial returns requirement	s for this product?			No	
	ADDITI	ONAL PROPUST INF	ODMATION			PROPUST PER	DESTINATION INCODES ATION	1						
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product (	(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	Neither		Size:	90 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status					Init	tial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	10mg			ORDER INFORM	ATION			
if yes, list NDCs of component parts			FDA Approval Status				TABLETS			ORDER INFORM	IATION			
reverse numbered?		No				Dosage Form:	TABLETS	ll IIn	it of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 90		uiiit.	
latex-free?		Yes	Allergens Fresent				Round		Box/Carton			g. 1 Box of 1	) Vials)	
preservative-free?		No				Product Shape:			Ampule		(	<b>.</b> . <b>-</b>	,	
correctional institution block?		Yes				Decident Octor	White		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube				'	
Cannabinoid?		No	Country of Origin	IN		Product Imprint:	J / 10		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					r roduct imprint.			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u						Vial Powder Sql		48	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ΓAA)?	No				Vial Power Multi			Inner/Carton	/Pack	
								<u> </u>	Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS										
			FOR GENERIC DRUG PRO	DDUCTS						A DM A OV ODDED	/DULLINIT			
			FOR GENERIC DRUG PRO	ODUCTS	Au		Authorized Generic, other			ARMACY ORDER				
I. Orange Book Rating:	АВ		FOR GENERIC DRUG PR	DDUCTS	Au		Authorized Generic, other tion fields are not applicable	Rec. sell unit to c	ustomer?	ARMACY ORDER	Rx billing u		асу:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Aricept	FOR GENERIC DRUG PRO	DDUCTS	Au			1 bottle	e of 90 tablets	ARMACY ORDER		Each	асу:	
		Aricept							e of 90 tablets	ARMACY ORDER	Rx billing u	Each Gram	асу:	
		Aricept	FOR GENERIC DRUG PRO					1 bottle	e of 90 tablets	ARMACY ORDER	Rx billing u	Each	асу:	
II. Generic Equivalent to What Bra	and?:	Aricept  DRUG SUPPLY	CHAIN SECURITY ACT (		RMATION	sec		1 bottle	e of 90 tablets ial)		Rx billing u	Each Gram Milliliter	асу:	
II. Generic Equivalent to What Bra	and?:	Aricept  DRUG SUPPLY	CHAIN SECURITY ACT (					1 bottle	e of 90 tablets ial)	ARMACY ORDER	Rx billing u	Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?:	Aricept  DRUG SUPPLY	CHAIN SECURITY ACT (		RMATION GLN:	8902805000006		1 bottle	e of 90 tablets ial)	AND PACKING IN	Rx billing u X  FORMATION	Each Gram Milliliter		
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?  If yes, select exemption:	and?:	Aricept  DRUG SUPPLY	CHAIN SECURITY ACT (		RMATION	sec		1 bottle	e of 90 tablets ial)	AND PACKING IN	Rx billing under X  NFORMATION Ons (US msn	Each Gram Milliliter	Volume	Saleable #
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	Aricept  DRUG SUPPLY	CHAIN SECURITY ACT (I Yes No		RMATION GLN: GCP:	8902805000006 0359746		1 bottle (Write-in, e.g. 1 V	e of 90 tablets ial)  ITEM  Weight Lbs.	AND PACKING IN  Dimensi  Depth	Rx billing under X  IFORMATION ons (US msm Width	Each Gram Milliliter  hts.) Height	Volume (Cube)	Saleable #
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Version 2021

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

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 b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No c. Contact Hazard? No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number Is there a REMS on this product? b. Proper Shipping Name c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Med Guide Required No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Site Enrollment Number assigned NCPDP# Limited Quantity Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS 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 Ship Product	Standard Order Receipt and Processing					
Purchase orders may be accepted by:  a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time:  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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:	Overnight receipt available:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday					
Class of Trade Restriction:  No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:  Other Data Information Required to Process PO:	Priority Overnight receipt available:  PO Receipt Cut off time:  Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply:  Other fees apply:  Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	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?					
	ADDITIONAL INFORMATION  Is product order for scheduled patient procedure? Is product order for restocking purposes?					