

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

						Introduction Ty	pe: Post Launch Change		x Final Version			Date:	7/12/	/2021
			PRODUCT INFORMAT	ΓΙΟΝ					SPECIAL HAND	LING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Jubilant Cadista F	harmaceuticals Inc.				Application	on: ANDA	a. Temperatur	re - Indicate the USP temper	rature range for th	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 090768						7.00	7.1.071			Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical		iii uu ru(ii)(iiiuu uu iii	-						Tomporataro rtango				,	
DUNS:	022490515				1				Other Temperature Range R	equirement				
Proprietary Name (If Applicable) a		me: Donep	ezil HCl Tablets						(write in)	oquiiomon				
Selling Unit NDC:	59746-329-30		Unit of Use NDC:			UPC:	3-59746-329-30-3		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Donanazii Hydroc	hloride 5mg 30ct Tab	lot .						Is this product to be shipped	to quotomoro on i	202		No	1
Description.	Donepezii i iyuloo	monde only soci rab	GL						Is this product to be shipped				No	
Active Ingredient(s):		Donepezil Hydrochl	oride						is this product to be shipped	to customers on a	ary icc:		140	I
, touvo ingroutoria(o).		,						b. Contact for	temperature excursion que	stions:				
URL for Additional Product Inforn	mation:	www.cadista.com	n/products/full-product	t-list					Name:		Customer Se	ervice		
Address:	207 Kiley Drive		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			Address 2:			Number:		(800) 313-46			
City:	Salisbury				State:	MD	Zip : 21801	Group E-mail:			customer.	customer.service@cadista.com		
Key Contact:	Jackie Emershaw	w Ema			Email:	Jackie.Emershav	v@jubl.com							
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646		c. Special reg	ulations for product in any s	states?			No	
Product Therapeutic Classificatio	on:	Dementia Treatmen	t						Special returns requirements	for this product?			No	
					_									
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only				Protect product (unit of sal	e) from light?			No	Ī
a legend device?		No	Is the Product	Neither			30 count	e. Shelf life:		,			24	Months
if yes, enter class #		1.14	Orphan Drug Status			Size:			Initial shelf life at launch (if	different):				Months
a product kit?		No	. •			Ot	5mg		•	•				
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	IATION			
component parts						Dosage Form:	TABLETS							
reverse numbered?		No				Dosage i oilii.			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					_	X Bottle		1 bottle of 30			
latex-free?		Yes				Product Shap	Round		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No				oudot onap			Ampule					
correctional institution block?		Yes				Product Color	White		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	IN		Product Impri	J / 5		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					-			Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u Trade Agreements Act (1	nder the					Vial Powder Sql		48	Each		
If Unit Dose, indicate NDC here:								11	10.15					
· ·			Trade Agreements Act (1	ГАА)?	No				Vial Power Multi			Inner/Cartor	/Pack	
					No				Vial Power Multi Other: Write In			Inner/Cartor Case	/Pack	
			FOR GENERIC DRUG PRO		No								/Pack	
						the size of Connection 12	III Authorized Copering other		Other: Write In	ARMACY ORDER			/Pack	
							"If Authorized Generic, other		Other: Write In	RMACY ORDER	/ BILL UNIT	Case		
I. Orange Book Rating:	AB						If Authorized Generic, other section fields are not applicable	Rec. sell unit	Other: Write In PHA to customer?	RMACY ORDER	/ BILL UNIT	Case		
		Aricept						1 b	Other: Write In PHA to customer? ottle of 30 tablets	ARMACY ORDER	/ BILL UNIT	Case nit to pharm Each		
I. Orange Book Rating:			FOR GENERIC DRUG PRO	DDUCTS	Au			_	Other: Write In PHA to customer? ottle of 30 tablets	ARMACY ORDER	/ BILL UNIT	Case nit to pharm Each Gram		
I. Orange Book Rating:				DDUCTS	Au			1 b	Other: Write In PHA to customer? ottle of 30 tablets	IRMACY ORDER	/ BILL UNIT	Case nit to pharm Each		
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Version 2021

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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 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



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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?					