

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

Version 2021						Introduction T	ype: P	ost Launch Change		x Final Version			Date:	5/1/2	2023
			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/AN	ANDA/BLA (drug); PMA/510(k)(med device): 090839								nperature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)		
Medical Device Class, if applicable:															
DUNS:	022490515							Other Temperature Range Requirement							
Proprietary Name (If Applicable) a		ame: Risperi	done ODT		1	1100				(write in)					
Selling Unit NDC: UDI	59746-030-22		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-59746-03	0-22-3	Not	es					
						MITA OOUC.									
Description:	Risperidone Oral	Disintegrating Tablets	2mg 28ct							his product to be shipped				No No	
Active Ingredient(s): Risperidone															
URL for Additional Product Information: www.cadista.com/products/full-product-list b. Contact for temperature excursion questions: Name: Customer Service															
Address:	207 Kiley Drive	www.cauista.com		-1150		Address 2:				nber:		(800) 313-46			
City:	Salisbury					MD	Zip: 218	301	Group E-mail: customer.service@cadista.com					dista.com	
Key Contact:	Customer Servic	e			Email:	customer.servi	ice@cadist	a.com							
Phone Number:	(800) 313-4623				Fax:	N/A			c. Special regulations for product in any states? No						
Product Therapeutic Classification	n:	Antipsychotic							Spe	cial returns requirement	s for this product?			No	
	ADDIT	IONAL PRODUCT INF				PRODUCT	DESCRIPTIO	N INFORMATION	d Store product (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	Inly					tect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither	in y		28 c	ount	e. Shelf life:	teet product (unit of sa	ne) nom ngnt :			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	20 00	Junt		al shelf life at launch (if different):			24	Months
a product kit?		No				Strength:	2mg								
if yes, list NDCs of			FDA Approval Status			Su'engui.					ORDER INFORM	NATION			
component parts						Dosage Form	n: TAB	LET, ODT				What is the			
reverse numbered? co-licensed?		No	Allergens Present						Uni	t of Sale Bottle		1 carton of 2		unit?	
latex-free?		Yes	Allergens Fresent				Rour	nd, Flat		X Box/Carton			g. 1 Box of 1) Vials)	
preservative-free?		No				Product Shap	pe:	,.		Ampule		(J		
correctional institution block?		Yes				Product Colo	Blue			Glass		Minimum or	der quantity	?	Yes
opioid?		No				r rouuct colo				Tube				-	
Cannabinoid?		No	Country of Origin	IN		Product Impr	rint: C / 0	3		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u hospital scanning?	init dose for		Is this product covered u	ndor the						Vial Liquid Multi Vial Powder Sql		If Yes, how 48	many of whi Each	ch package t	ype?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No					Vial Power Multi			Inner/Carton	/Pack	
				,.						Other: Write In			Case	don	
			FOR GENERIC DRUG PRO	ODUCTS		•									
					A	uthorized Generic		ed Generic, other			ARMACY ORDER				
I. Orange Book Rating: AB					section fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Risperdal®								of 28 tablets		X	Each Gram				
	DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Write-in, e.g. 1 Vial) Gram														
				,											
Does supplier meet DSCSA defini	tion of manufactu	irer?	Yes		GLN:	8902805000006				ITEN	I AND PACKING I	NFORMATION	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ons (US msm	,		Saleable #
Other exemption - Write in:			No		W	data da ante de la					Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	ovclusivo distrib	utor?	No	-	If yes, was o direct from n	riginal product purc	chased		Item/Each:	0.05	1.9	1.9	4	14.44	1
Has FDA granted waiver/exception			No	-		rce manufacturer fo	r repackage	d product	Box/Carton/Bundl	e/					
If yes, attach documentation from									Inner Pack:					0.00	
									Case:	4.5	21.46	18.5	10.31	4093.17	48
		GTIN	NAND HIBCC PRODUCT IN	FORMATION					Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		GT	IN-14	Uni	it of Use GTIN-14	Pallet:					0.00	
X Item/Each	·	1				359746030223									
Box/Carton/Bundle/Inner Pack									WHOLESALER USE ONLY:						
X Case		48			403	359746030221									
Pallet									Regular Cost			Vendor #:			
	-						-		Invoice Cost (WA	5) (\$)	\$93.52	Whsl. Code			
	-				-		-		As of date:			Fineline Co	ue:		
					-				As of udle.			1			
	-														
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE	INSERT, LA	BEL AND PHOTO OF P	RODUCT PACKAGIN	G and BARCODE.		•			
*Please provide any additional inf	ormation on page					See new p. 3 for				nature:					

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

Version 2021 Fo	or Designated Drop Ship Only Products, Please Use Page 3
MAT	FERIAL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? 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? Does the product label bear a CA Prop 65 warning? 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?	No SDS Hazard Classification No Organic Corrosive No Inorganic Oxidizer No Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No No NFPA Storage Level: Image: Contact Hazard
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 the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which: Hazardous Waste Identification Image: No EPA Hazardous Waste Code: Waste Characteristics
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? 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	No REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? No Website URL: No No Med Guide Required Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) No REMS: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned DEA #:
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	by Supplier: NPI #: Comments
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION: No CLASS OF TRADE RESTRICTION:	No RETURN INSTRUCTIONS No Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:
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:	Yes Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? SCELLANEOUS 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: Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?