

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

Version 2021						Introduction T	ype:	Post Launch Change		x F	inal Version			Date:	5/1/	/2023	
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENT					REMENTS*					
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.											
Application Number for NDA/AN			ce):	090	1839					Temperatu		Controlled Room		and 25 C (68	8° – 77° F)		
Medical Device Class, if applica	ble:																
DUNS:	022490515										perature Range F	Requirement					
Proprietary Name (If Applicable)		ame: Risper	ridone ODT							(write	in)						
Selling Unit NDC: UDI	59746-050-22		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-59746-	-050-22-1		Notes							
_						INIVA Code.			:				_				
Description: Risperidone Oral Disintegrating Tablets 4mg 28ct										to customers on i			No	-			
Active Ingredient(s): Risperidone Is this product to be shipped to customers on dry ice? No																	
Active ingredients).						b. Contact for temperature excursion questions:											
URL for Additional Product Inforr	nation:	www.cadista.co	m/products/full-product	-list						Name:				Customer Service			
Address:	207 Kiley Drive					Address 2:				Number:			(800) 313-4				
City:	Salisbury				MD	Zip:		Group E-mail:			customer.service@cadista.com						
Key Contact: Phone Number:	(800) 313-4623				Email: Fax:	customer.service@cadista.com N/A			c. Special regulations for product in any states?				No				
Product Therapeutic Classification		Antipsychotic			ı ax.	IVA			c. Special reg	-		s for this product?	No				
Troduct Therapeutic Glassification	//··	ranipayonone								Opecial reti	ums requirement	s for this product:			140		
	ADDIT	IONAL PRODUCT IN	IFORMATION			PRODUCT D	DESCRIP	TION INFORMATION	d. Store prod	duct (unit of	sale) upright?				No	1	
The product is?			Is the Product	Direct-Ship O	nlv					-	oduct (unit of sa	le) from light?			No	1	
a legend device?		No	Is the Product	Neither	,		2	8 count	e. Shelf life:	r rotect pro	oduct (dilit of se	iie) iioiii iigiit:			24	Months	
if yes, enter class #		11.12	Orphan Drug Status			Size:	-			Initial shel	f life at launch (if different):				Months	
a product kit?		No				Strength:	41	mg									
if yes, list NDCs of			FDA Approval Status			Ou chigan.						ORDER INFORM	MATION				
component parts reverse numbered?		NI.				Dosage Form	n: T	ABLET, ODT		Unit of Sal	_		What is the	NDC selling	. unit?		
co-licensed?		No No	Allergens Present								e ottle		1 carton of 2		juilitr		
latex-free?		Yes	Allergens i resent				R	lound, Flat			ox/Carton			g. 1 Box of 1	0 Vials)		
preservative-free?		No				Product Shap	pe:				mpule				,		
correctional institution block?		Yes				Product Colo	P	ink		G	lass		Minimum o	rder quantity	y?	Yes	
opioid?		No									ube						
Cannabinoid?	and deep fee	No	Country of Origin	IN		Product Impr	rint:	: / 05			ial Liquid Sgl ial Liquid Multi		If Van ham		lab maalsassa	h	
If Unit Dose, is item bar coded to hospital scanning?	unit dose for		Is this product covered u	nder the							ial Powder Sql			Each	ich package	type?	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No						ial Power Multi			Inner/Cartor	n/Pack		
				,							ther: Write In			Case			
			FOR GENERIC DRUG PRO	ODUCTS										_			
					Au	thorized Generic		rized Generic, other	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:				section fields are not applicable				Rec. sell unit to customer?				Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: Risperdal®							1 carton of 28 tablets (Write-in, e.g. 1 Vial)			X Each Gram							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						(write-in, e.g. 1 viai) Milliliter											
				, , , , , , , , , , , , , , , , , , , ,													
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes		GLN:	8902805000006					ITEN	I AND PACKING II	NFORMATIO	N			
Is product exempt from DSCSA?			No														
If yes, select exemption:					GCP:	0359746					Weight Lbs.	Dimensi	ions (US msr	nts.)	Volume	Saleable #	
Other exemption - Write in:											Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?		10	No	_		riginal product purc	hased		Item/Each:		0.05	1.9	1.9	4	14.44	1	
Is product sold by manufacturer's Has FDA granted waiver/exception			No No	+	direct from m	nfr? ce manufacturer foi	r ransaks	aged product	Box/Carton/E	Rundle/							
If yes, attach documentation fro		TOUUCE:	110		r rovide sour	ce manufacturer for	Гераска	igeu product	Inner Pack:	Dullule/					0.00		
									Case:		4.4	21.46	18.5	10.31	4093.17	48	
		GTI	IN AND HIBCC PRODUCT IN	NFORMATION							4.4	21.40	10.5	10.31	4093.17	40	
									Pallet:						0.00		
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC			N-14	1 1	Unit of Use GTIN-14									
X Item/Each Box/Carton/Bundle/Inner Pack						COST INFORMATION WHOLESALER USE ONLY:						Y:					
X Case								- Ortmarrion			OLLOAL	LIN GOL ONE					
Pallet									Regular Cost	t			Vendor #:				
									Invoice Cost	(WAC) (\$)		\$254.57	Whsl. Code				
										_			Fineline Co	de:			
	_						-		As of date:				-				
μ				TA OLIFET (OD	0)		INIOEDT	LABEL AND PHOTO OF P	DODLICT DACK	14 OINO 1 F	ARCORE		1				
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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? No	Organic Corrosive Inorganic Oxidizer							
Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	Inorganic Oxidizer Steroid/Androgen Contact Hazard							
boes the product label bear a OATTOP to warning:	Ornaci Tazard							
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No							
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:							
(If yes, attach SDS with special instructions.)	NFPA Storage Level:							
e. Does the product contain DEHP?								
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?							
(if yes, answer a-e below and provide SDS)	If yes, indicate which:							
a. UN/Identification Number b. Proper Shipping Name								
c. DOT Hazard Class	Hazardous Waste Identification							
d. Packing Group								
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics							
Is this product regulated for shipment by IATA?								
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS							
a. UN/Identification Number								
b. Proper Shipping Name	Is there a REMS on this product?							
c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry? Website URL:							
e. Inhalation Hazard?	Website ORL.							
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? No	REMS:							
RQ Threshold:	REMS Program Manager Name: Phone:							
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:							
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:							
No (if yes, identify method below) Limited Quantity	Provider Name: DEA #: Site Enrollment Number assigned NCPDP#:							
Consumer Commodity, ORM-D	by Supplier: NPI #:							
Small Quantity (49 CFR 173.4)								
Special Permit; DOT-SP	Comments							
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#	Registry:							
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:							
	Comments							
Is the Product Controlled Substance 2	RETURN INSTRUCTIONS							
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	KETORI NOTIONS							
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:	Consider outletions or returns continued for this							
Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states?							
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?							
Comments:								
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:							
- INIGCLELAT								



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method fo	r Designated Drop Ship Product	Standard Order Receipt and Processing					
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:					
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:					
F	Name: Phone:	Ships regular ground for 3-10 days receipt:					
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:		Overnight receipt available:					
Drop Ship service fee billed with each order:		PO Receipt cut off time:					
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday					
		Priority Overnight receipt available:					
Class	of Trade Restriction:	PO Receipt Cut off time:					
No restriction: Select YES if sold to retail pharmacy only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Infor	rmation Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?					
Mis	scellaneous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure? Is product order for restocking purposes?					