



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 6/17/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc.		Application: ANDA		<b>a. Temperature – Indicate the USP temperature range for this product.</b>			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 090839				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: 022490515		Proprietary Name (If Applicable) and Established Name: Risperidone ODT		Notes: <input type="text"/>			
Selling Unit NDC: 59746-050-22		Unit of Use NDC:		Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
UDI:		CVX Code:		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
Description: Risperidone Oral Disintegrating Tablets 4mg 28ct		MVX Code:		<b>b. Contact for temperature excursion questions:</b>			
Active Ingredient(s): Risperidone				Name: Customer Service			
URL for Additional Product Information: <a href="http://www.cadista.com/products/full-product-list">www.cadista.com/products/full-product-list</a>				Number: (800) 313-4623			
Address: 790 Township Line Road		Address 2: Suite 325		Group E-mail: <a href="mailto:customer.service@cadista.com">customer.service@cadista.com</a>			
City: Yardley		State: PA					
Key Contact: Customer Service		Zip: 19067		<b>c. Special regulations for product in any states?</b>			
Phone Number: (800) 313-4623		Email: <a href="mailto:customer.service@cadista.com">customer.service@cadista.com</a>		Special returns requirements for this product? <input type="checkbox"/> No			
Product Therapeutic Classification: Antipsychotic		Fax: N/A		<b>d. Store product (unit of sale) upright?</b> <input type="checkbox"/> No			
				<b>e. Shelf life:</b>			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				Initial shelf life at launch (if different): <input type="text"/> 24 Months			
<b>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>			
The product is a legend device? <input type="checkbox"/> No		Is the Product... Direct-Ship Only <input type="checkbox"/>		Size: 28 count			
if yes, enter class # a product kit? <input type="checkbox"/> No		Is the Product... Orphan Drug Status <input type="checkbox"/>		Strength: 4mg			
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No		FDA Approval Status <input type="text"/>		Dosage Form: TABLET, ODT			
co-licensed? <input type="checkbox"/> No		Allergens Present <input type="text"/>		Product Shape: Round, Flat			
latex-free? <input type="checkbox"/> Yes		Country of Origin: IN		Product Color: Pink			
preservative-free? <input type="checkbox"/> No		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		Product Imprint: C / 05			
correctional institution block? <input type="checkbox"/> Yes							
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
<b>FOR GENERIC DRUG PRODUCTS</b>				<b>ORDER INFORMATION</b>			
I. Orange Book Rating: AB		<input type="checkbox"/> Authorized Generic		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Risperdal®				Unit of Sale: <input checked="" type="checkbox"/> Bottle, <input type="checkbox"/> Box/Carton, <input type="checkbox"/> Ampule, <input type="checkbox"/> Glass, <input type="checkbox"/> Tube, <input type="checkbox"/> Vial Liquid Sgl, <input type="checkbox"/> Vial Liquid Multi, <input type="checkbox"/> Vial Powder Sgl, <input type="checkbox"/> Vial Power Multi, <input type="checkbox"/> Other: Write In			
				What is the NDC selling unit? 1 carton of 28 tablets (Write-in, e.g. 1 Box of 10 Vials)			
				Minimum order quantity? <input type="checkbox"/> Yes			
				If Yes, how many of which package type? 48 Each, Inner/Carton/Pack, Case			
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>				<b>PHARMACY ORDER / BILL UNIT</b>			
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: 8902805000006		Rec. sell unit to customer? 1 carton of 28 tablets (Write-in, e.g. 1 Vial)			
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: 0359746		Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each, <input type="checkbox"/> Gram, <input type="checkbox"/> Milliliter			
If yes, select exemption: Other exemption - Write in: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Is product repackaged? <input type="checkbox"/> No		Provide source manufacturer for repackaged product: <input type="text"/>					
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No							
Has FDA granted waiver/exemption/exemption for product? <input type="checkbox"/> No							
If yes, attach documentation from FDA: <input type="text"/>							
<b>GTIN AND HIBCC PRODUCT INFORMATION</b>				<b>ITEM AND PACKING INFORMATION</b>			
Saleable Unit of Measure: <input checked="" type="checkbox"/> Item/Each, <input type="checkbox"/> Box/Carton/Bundle/Inner Pack, <input checked="" type="checkbox"/> Case, <input type="checkbox"/> Pallet		Saleable Quantity: 1, 48		HIBCC: <input type="text"/>		Dimensions (US msmts.): Depth, Width, Height	
				GTIN-14: 00359746050221, 40359746050229		Volume (Cube): 14.44, 4093.17, 0.00	
				Unit of Use GTIN-14: <input type="text"/>		Saleable # Pieces: 1, 48	
<b>COST INFORMATION</b>				<b>WHOLESALE USE ONLY:</b>			
Regular Cost: <input type="text"/>		Invoice Cost (WAC) (\$): \$254.57		Vendor #: <input type="text"/>		Whsl. Code #: <input type="text"/>	
As of date: <input type="text"/>				Fineline Code: <input type="text"/>			
*Please provide any additional information on page 2.				Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.			
				See new p. 3 for Designated Drop Ship Only.			
				Signature: <input type="text"/>			



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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
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - 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? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  No

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 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?  No

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

- Passenger  No
- Cargo  No
- Passenger & Cargo  No

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  Yes
- Controlled Substance Code
- Controlled by State(s)?  No  Yes
- Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes
- If yes, indicate which:
- Schedule No.
- Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No  
NFPA Storage Level:

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

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
If Yes, is it managed with a pharmacy registry?   
Website URL:

Med Guide Required  No  
Limited Distribution Requirement  No  
Comments / Details: (For example, iPledge program?)

**REMS:**  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:   
Wholesale distributor support:   
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
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:



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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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	
<p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>