



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

Version 2021 Introduction Type: Post Launch Change Final Version Date: 5/1/2023

PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 090839
 Medical Device Class, if applicable:
 DUNS: 022490515
 Proprietary Name (If Applicable) and Established Name: Risperidone ODT
 Selling Unit NDC: 59746-020-22 Unit of Use NDC: UPC: 3-59746-020-22-4
 UDI CVX Code: MVX Code:
 Description: Risperidone Oral Disintegrating Tablets 1mg 28ct
 Active Ingredient(s): Risperidone
 URL for Additional Product Information: www.cadista.com/products/full-product-list
 Address: 207 Kiley Drive Address 2:
 City: Salisbury State: MD Zip: 21801
 Key Contact: Customer Service Email: customer.service@cadista.com
 Phone Number: (800) 313-4623 Fax: N/A
 Product Therapeutic Classification: Antipsychotic

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement (write in):
 Notes:
 Is this product to be shipped to customers on ice? No
 Is this product to be shipped to customers on dry ice? No
 b. Contact for temperature excursion questions:
 Name: Customer Service
 Number: (800) 313-4623
 Group E-mail: customer.service@cadista.com
 c. Special regulations for product in any states?
 Special returns requirements for this product? No
 d. Store product (unit of sale) upright? No
 Protect product (unit of sale) from light? No
 e. Shelf life:
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

The product is a legend device? No
 if yes, enter class # a product kit? No
 if yes, list NDCs of component parts reverse numbered? No
 co-licensed? No
 latex-free? Yes
 preservative-free? No
 correctional institution block? Yes
 opioid? No
 Cannabinoid? No
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose, indicate NDC here:
 Is the Product... Direct-Ship Only
 Is the Product... Orphan Drug Status
 FDA Approval Status:
 Allergens Present:
 Country of Origin: IN
 Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 28 count
 Strength: 1mg
 Dosage Form: TABLET, ODT
 Product Shape: Round, Flat
 Product Color: White
 Product Imprint: C / 02

ORDER INFORMATION

Unit of Sale: Bottle, Box/Carton, Ampule, Glass, Tube, Vial Liquid Sgl, Vial Liquid Multi, Vial Powder Sgl, Vial Power Multi, Other: Write In
 What is the NDC selling unit?
 (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity? Yes
 If Yes, how many of which package type?
 Each
 Inner/Carton/Pack
 Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
 Is product exempt from DSCSA? No
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged? No
 Is product sold by manufacturer's exclusive distributor? No
 Has FDA granted waiver/exception/exemption for product? No
 If yes, attach documentation from FDA.
 GLN: 8902805000006
 GCP: 0359746
 If yes, was original product purchased direct from mfr?
 Provide source manufacturer for repackaged product:

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.05	1.9	1.9	4	14.44	1
Case:	4.45	21.46	18.5	10.31	4093.17	48
Pallet:					0.00	

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00359746020224	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		40359746020222	
<input type="checkbox"/> Pallet				

COST INFORMATION

Regular Cost:
 Invoice Cost (WAC) (\$):
 As of date:
 Vendor #:
 Whsl. Code #:
 Finline Code:



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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:

