

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

						Introduction Type:	Post Launch Change		x Final Version			Date:	3/1/2	2023
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Jubilant Cadista F	Pharmaceuticals Inc.				Application:	ANDA	a. Temperatui	re - Indicate the USP temp	erature range for ti	nis product.			
Application Number for NDA/AN	IDA/BLA (drug); Pl	MA/510(k)(med devic	e):	090839				† I	Temperature Range	Controlled Room -	- between 20	and 25 C (68	, – 77° F)	
Medical Device Class, if applica														
DUNS:	022490515								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	ame: Risperi	idone ODT						(write in)					
Selling Unit NDC:	59746-020-22		Unit of Use NDC:			UPC: 3-59	746-020-22-4	.	Notes					
UDI			CVX Code:			MVX Code:								
Description:	Risperidone Oral	Disintegrating Tablets	1mg 28ct						Is this product to be shippe				No	
		1							Is this product to be shippe	d to customers on d	ry ice?		No	
Active Ingredient(s):		Risperidone						h Cambant fan	r temperature excursion qu					
URL for Additional Product Inform	nation:	www.cadista.cor	m/products/full-produc	+_lict				b. Contact for	r temperature excursion qu Name:	estions:	Customer Se	nvice		
Address:	207 Kiley Drive	www.cadista.com	il products/ run produc	t-list		Address 2:		†	Number:		(800) 313-46			
City:	Salisbury				State:		21801		Group E-mail:		customer.s		dista.com	
Key Contact:	Customer Service	Э			mail:	customer.service@d	cadista.com							
Phone Number:	(800) 313-4623				Fax:	N/A		c. Special reg	julations for product in any	states?			No	
Product Therapeutic Classification	on:	Antipsychotic							Special returns requirement	ts for this product?			No	
								.						1
	ADDITI	IONAL PRODUCT INF	ORMATION			PRODUCT DESCI	RIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship Only					Protect product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	28 count	e. Shelf life:					24	Months
if yes, enter class # a product kit?		N.	Orphan Drug Status				4		Initial shelf life at launch	if different):				Months
if yes, list NDCs of		No	FDA Approval Status			Strength:	1mg			ORDER INFORM	IATION			
component parts			1 DA Approvar otatus				TABLET, ODT			511.5 <u>211.111.</u> 1011.11				
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 carton of 2	8 tablets		
latex-free?		Yes				Product Shape:	Round, Flat		X Box/Carton		(Write-in, e.	g. 1 Box of 1) Vials)	
preservative-free?		No							Ampule				_	
correctional institution block?		Yes				Product Color:	White		Glass		Minimum or	der quantity	?	Yes
opioid? Cannabinoid?		No No	Country of Origin	IN			C / 02		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	INU	Country of Origin	IIV		Product Imprint:	0702		Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?
hospital scanning?	unit dosc for		Is this product covered u	under the					Vial Powder Sql			Each	paonago :	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)? No					Vial Power Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Auth		uthorized Generic, other on fields are not applicable			IARMACY ORDER				
I. Orange Book Rating:	AB					Secu	on neids are not applicable		to customer?		Rx billing ur		ıcy:	
II. Generic Equivalent to What Bra	and?:	Risperdal®												
									arton of 28 tablets		Х	Each		
		DRUG SUPPI	Y CHAIN SECURITY ACT	(DSCSA) INFORMATIO	ON			(Write-in, e.g.			Х	Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT ((DSCSA) INFORMATIO	ON						X			
Does supplier meet DSCSA defini	ition of manufactur		Y CHAIN SECURITY ACT ((DSCSA) INFORMATIO		8902805000006			1 Vial)	// AND PACKING IN		Gram Milliliter		
Does supplier meet DSCSA definition Is product exempt from DSCSA?	ition of manufactur					8902805000006			1 Vial)	II AND PACKING IN		Gram Milliliter		
	ition of manufactu		Yes			8902805000006 0359746			1 Vial)			Gram Milliliter	Volume	Saleable #
Is product exempt from DSCSA?	ition of manufactu		Yes No	GLN:					1 Vial)		NFORMATION	Gram Milliliter	Volume (Cube)	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		rer?	Yes No	GLN: GCP:	, was ori	0359746 ginal product purchase	d		1 Vial) ITEL Weight Lbs.	Dimensi Depth	NFORMATION ons (US msm Width	Gram Milliliter	(Cube)	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distribu	rer?	Yes No No	GLN: GCP: If yes direct	i, was oriq t from mf	0359746 ginal product purchaserr?		(Write-in, e.g.	1 Vial) Weight Lbs. 0.05	Dimensi	NFORMATION	Gram Milliliter		Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distribu	rer?	Yes No	GLN: GCP: If yes direct	i, was oriq t from mf	0359746 ginal product purchase		(Write-in, e.g.	1 Vial) Weight Lbs. 0.05	Dimensi Depth	NFORMATION ons (US msm Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distribu	rer?	Yes No No	GLN: GCP: If yes direct	i, was oriq t from mf	0359746 ginal product purchaserr?		(Write-in, e.g. Item/Each: Box/Carton/B Inner Pack:	Weight Lbs. 0.05	Dimensi Depth 1.9	ons (US msm Width	Gram Milliliter	(Cube) 14.44 0.00	Pieces 1
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distribu on/exemption for pr m FDA.	utor?	Yes No No No No	GLN: GCP: If yes direct	i, was oriț t from mf de source GTIN	0359746 ginal product purchaser? e manufacturer for repa		Item/Each: Box/Carton/B Inner Pack: Case:	Weight Lbs. 0.05	Dimensi Depth 1.9	ons (US msm Width	Gram Milliliter	(Cube) 14.44 0.00	Pieces 1
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X Item/Each Bow/Carton/Bundle/Inner Pack X Case	s exclusive distribu on/exemption for pr m FDA.	rer? utor? roduct? GTIN	Yes No No No No No No	GLN: GCP: If yes direct	i, was oriț t from mf de source GTIN 0035	0359746 ginal product purchaser? e manufacturer for repa	ckaged product	Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	1 Vial) Weight Lbs. 0.05 Sundle/ 4.45 COST INFORMATION	Dimensi Depth 1.9	Vendor #:	Gram Milliliter Its.) Height 4 10.31	(Cube) 14.44 0.00 4093.17 0.00	Pieces 1 48
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X Item/Each Bow/Carton/Bundle/Inner Pack X Case	s exclusive distribundexemption for pr m FDA.	rer? utor? roduct? GTIN Saleable Quantity 1 48	No No No No No HIBCC	GLN: GCP: If yes direct Provision INFORMATION	GTIN 0035	0359746 ginal product purchaser? e manufacturer for repa l-14 9746020224 9746020222	Unit of Use GTIN-14	Item/Each: Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost (As of date:	1 Vial) Weight Lbs. 0.05 Fundle/ 4.45 COST INFORMATION (WAC) (\$)	Dimensi Depth 1.9 21.46	Vendor #:	Gram Milliliter Its.) Height 4 10.31	(Cube) 14.44 0.00 4093.17 0.00	Pieces 1 48



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD 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					
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						



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

Version 2021

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

Order Method for Designated Drop S	nip 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: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?