

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

						Introduction Ty	pe: Post Launch Change		x Final Version			Date:	7/12/	12021
			PRODUCT INFORMAT	ΓΙΟΝ					SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Jubilant Cadista Ph	armaceuticals Inc.				Application	on: ANDA	a. Temperatu	re - Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/AN			a)·	09	90839	, ipp	7.1.57	- u. remperata		Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical			~,·						romporataro rtango				,	
DUNS:	022490515				T T				Other Temperature Range R	equirement				
Proprietary Name (If Applicable) a		ne: Risperi	done ODT						(write in)	oquiiomoni				
Selling Unit NDC:	59746-040-22		Unit of Use NDC:			UPC:	3-59746-040-22-2		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Pieneridone Oral D	isintegrating Tablets	3ma 28ct						Is this product to be shipped	to quotomore on in	202		No	1
Description.	Nisperidorie Orai D	isintegrating rabiets	Jing 2001						Is this product to be shipped				No	
Active Ingredient(s):		Risperidone							is this product to be shipped	to customers on u	ily ioc:		140	I
, touvo ingroutoria(o).								b. Contact for	r temperature excursion que	stions:				
URL for Additional Product Inforn	nation:	www.cadista.cor	n/products/full-product	t-list					Name:		Customer Se	ervice		
Address:	207 Kiley Drive					Address 2:			Number:		(800) 313-46	23		
City:	Salisbury		State:			MD	<b>Zip</b> : 21801		Group E-mail: customer.service@cadista.com			dista.com		
Key Contact:	Jackie Emershaw				Email:	Jackie.Emershav	w@jubl.com							
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646		c. Special reg	gulations for product in any	states?			No	
Product Therapeutic Classificatio	on:	Antipsychotic							Special returns requirements	for this product?			No	
					_									
	ADDITIO	NAL PRODUCT INF	ORMATION			PRODUCT DE	ESCRIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only				Protect product (unit of sal	e) from light?			No	Ī
a legend device?		No	Is the Product	Neither			28 count	e. Shelf life:	,	,			24	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (i	different):				Months
a product kit?		No				Ot	3mg			•				
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts						Dosage Form:	TABLET, ODT							
reverse numbered?		No				Dosage i oim.			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 carton of 2			
latex-free?		Yes				Product Shap	Round, Flat		X Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No						_	Ampule				_	
correctional institution block?		Yes				Product Color	Orange :		Glass		Minimum o	der quantity	?	Yes
opioid? Cannabinoid?		No	Country of Origin	IN			C / 04	_	Tube Vial Liquid Sql					
		No	Country of Origin	IIN		Product Impri	nt: C / 04		Vial Liquid Sgi Vial Liquid Multi		If Yes, how		ah maakama	4
If Unit Dose, is item bar coded to understand the hospital scanning?	unit dose for		Is this product covered u	nder the				-	Vial Powder Sql			Each	сп раскаде	type r
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	TAA)?	No				Vial Power Multi		40	Inner/Carton	/Pack	
ii onii bose, iidicate Nbo nere.	I.		]	,	140				Other: Write In			Case	71 dok	
			FOR GENERIC DRUG PRO	ODUCTS				<del>  </del>						
			FOR GENERIC DRUG PRO	DDUCTS										
			FOR GENERIC DRUG PRO	DDUCTS	Au	uthorized Generic	*If Authorized Generic, other			ARMACY ORDER	/ BILL UNIT			
L Orange Beat Patient	AD		FOR GENERIC DRUG PRO	DDUCTS	Au		"If Authorized Generic, other section fields are not applicable	Pop cell unit	PH	ARMACY ORDER				
I. Orange Book Rating:	AB		FOR GENERIC DRUG PRO	ODUCTS	Au			Rec. Sell ullit	PH/ to customer?	ARMACY ORDER	Rx billing u	nit to pharm	асу:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Risperdal	FOR GENERIC DRUG PRO	DDUCTS	Au			1 c	PH/ to customer? earton of 28 tablets	ARMACY ORDER		nit to pharm	acy:	
		Risperdal						Rec. Sell ullit	PH/ to customer? earton of 28 tablets	ARMACY ORDER	Rx billing u	nit to pharm Each Gram	acy:	
		Risperdal	FOR GENERIC DRUG PRO					1 c	PH/ to customer? earton of 28 tablets	RMACY ORDER	Rx billing u	nit to pharm	асу:	
	and?:	Risperdal  DRUG SUPPL						1 c	PH/ to customer? arton of 28 tablets 1 Vial)	ARMACY ORDER	Rx billing u	nit to pharma Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra	and?:	Risperdal  DRUG SUPPL	CHAIN SECURITY ACT (I		RMATION			1 c	PH/ to customer? arton of 28 tablets 1 Vial)		Rx billing u	nit to pharma Each Gram Milliliter	асу:	
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?:	Risperdal  DRUG SUPPL	CHAIN SECURITY ACT (E		RMATION GLN:	8902805000006		1 c	PH/ to customer? arton of 28 tablets 1 Vial)	AND PACKING IN	Rx billing u X IFORMATION	nit to pharm. Each Gram Milliliter		Saleable #
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II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	Risperdal  DRUG SUPPL	Y CHAIN SECURITY ACT (I Yes No		GLN: GCP: If yes, was o	8902805000006		1 c (Write-in, e.g.	PH/ to customer? arton of 28 tablets 1 Vial)	AND PACKING IN	Rx billing under X  IFORMATION Ons (US msn	nit to pharm Each Gram Milliliter	Volume	
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Version 2021

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

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? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No c. Contact Hazard? No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number Is there a REMS on this product? b. Proper Shipping Name c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No 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? REMS: RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Site Enrollment Number assigned NCPDP# Limited Quantity Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No 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: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



# **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 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:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday					
Class of Trade Restriction:  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:  Other Data Information Required to Process PO:	Priority Overnight receipt available:  PO Receipt Cut off time:  Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply:  Other fees apply:  Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	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?					
	ADDITIONAL INFORMATION  Is product order for scheduled patient procedure? Is product order for restocking purposes?					