

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

					Introduction Type:			Final Version			Date:	10/0/	2025
		PRODUCT INFORMA	ATION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name: Jubilant	Cadista Pharmaceu	uticals Inc.			Application:	ANDA	a. Temperature – Indica	ate the USP tempe	rature range for th	is product.			
Application Number for NDA/ANDA/BLA;		078828				IOT APPLICABLE		ture Range	Controlled Room -		and 25 C (68	, – 77° F)	
Medical Device Class, if applicable:	1	3.											
DUNS: 118694	41						Other Te	mperature Range F	tequirement				
Proprietary Name (If Applicable) and Estab		Risperidone						ite in)	•				
Selling Unit NDC: 59746-0		Unit of Use NDC	:		UPC: 3-59746-	225-05-6	Notes	•					
UDI		CVX Code:			MVX Code:								
Description: Risperidone Tablets 3mg 500ct							le this nr	nduct to be shinner	to customers on ic	62		No	
Traportion Tubica only 5000									to customers on dr			No	
Active Ingredient(s): Risperidone						1			•				
11							b. Contact for temperat	ture excursion que	stions:				
URL for Additional Product Information:	www.c	adista.com/products/full-produc	t-list				Name:			Customer Se	rvice		
	nship Line Road				Address 2: Suite 325		Number:	:		(800) 313-46			
	Yardley State: PA Zip: 19067						Group E-mail: <u>customer.service@cadista.com</u>						
Phone Number: (800) 31				Fax:	N/A		c. Special regulations f					No	
Product Therapeutic Classification:	Antipsyc	hotic					Special r	eturns requirement	s for this product?			No	
	ADDITIONAL PR	ODUCT INFORMATION			PRODUCT DESCRIPT	TON INFORMATION	d. Store product (unit o	of sale) upright?				No	
The product is?		Is the Product	Direct-Ship Onl	ly			Protect p	product (unit of sa	le) from light?			No	
a legend device?	No	Is the Product	Neither		Size:	0 count	e. Shelf life:					24	Months
if yes, enter class #		Orphan Drug Status					Initial sh	elf life at launch (i	f different):				Months
a product kit?	No				Strength: 3n	ng			ODDED INFORM	ATION			
if yes, list NDCs of		FDA Approval Status			T	ABLET			ORDER INFORM	ATION			
reverse numbered?	No				Dosage Form:	ADLEI	Unit of S	talo.		What is the	NDC salling	unit?	
co-licensed?	No	Allergens Present						Bottle		1 bottle of 50			
latex-free?	Yes	Anergens i resent			Ca	apsule		Box/Carton			a. 1 Box of 10) Vials)	
preservative-free?	No				Product Shape:			Ampule		(******************	, =	,	
correctional institution block?	Yes				Product Colon	ellow		Glass		Minimum or	der quantity	?	Yes
opioid?	No				Product Color:			Tube				,	
Cannabinoid?	No	Country of Origin	USA		Product Imprint:	225		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unit dose f	or				1 Todaot IIIIpiintii			Vial Liquid Multi			•	ch package t	ype?
hospital scanning?		Is this product covered						Vial Powder Sql		12	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (IAA)?	r'es				Vial Power Multi			Inner/Carton	Pack	
<u> </u>								Other: Write In			Case		
		FOR GENERIC DRUG PF	RODUCIS										
				۸	havined Canasia *If Author	izad Canaria athar		DH	APMACY OPDER	/ RILL LINIT			
				Aut		ized Generic, other			ARMACY ORDER				
I. Orange Book Rating: AB				Aut		rized Generic, other elds are not applicable	Rec. sell unit to custom	ner?		Rx billing u		cy:	
I. Orange Book Rating: II. Generic Equivalent to What Brand?:	Risperda			Aut			1 bottle of 500	ner?			Each	cy:	
		al@	(DSCSA) INFORM				1 bottle of 500 (Write-in, e.g. 1 Vial)	ner?		Rx billing u	Each Gram	ıcy:	
			(DSCSA) INFORM				1 bottle of 500	ner?		Rx billing u	Each	ıcy:	
II. Generic Equivalent to What Brand?:	DR	UG SUPPLY CHAIN SECURITY ACT		IATION	section fi		1 bottle of 500 (Write-in, e.g. 1 Vial)	ner? O tablets		Rx billing u	Each Gram Milliliter	ncy:	
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of m	DR	al@					1 bottle of 500 (Write-in, e.g. 1 Vial)	ner? O tablets		Rx billing u	Each Gram Milliliter	ıcy:	
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of m Is product exempt from DSCSA?	DR	ug Supply Chain Security act Yes		IATION GLN:	section file		1 bottle of 500 (Write-in, e.g. 1 Vial)	ner? O tablets	AND PACKING IN	Rx billing un X	Each Gram Milliliter		Salaahla #
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of m Is product exempt from DSCSA? If yes, select exemption:	DR	ug Supply Chain Security act Yes		IATION	section fi		1 bottle of 500 (Write-in, e.g. 1 Vial)	ner? O tablets	AND PACKING IN	Rx billing un X FORMATION	Each Gram Milliliter	Volume	Saleable #
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of m Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	DR	ug supply chain security act Yes No		MATION GLN: GCP:	0359746000004		1 bottle of 500 (Write-in, e.g. 1 Vial) HCPCS J-Code:	ner? 0 tablets ITEM Weight Lbs.	AND PACKING IN Dimensic Depth	Rx billing un X FORMATION Ons (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of m Is product exempt from DSCSA? If yes, select exemption:	DR	ug Supply Chain Security act Yes	G	MATION GLN: GCP:	0359746000004 0359746 ginal product purchased		1 bottle of 500 (Write-in, e.g. 1 Vial)	ner? 0 tablets ITEM	AND PACKING IN	Rx billing un X FORMATION	Each Gram Milliliter	Volume	
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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): SDS Hazard Classification a. Cytotoxic? No 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? Oxidizer No Inorganic 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 No 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 2024

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					
	Priority Overnight receipt available:					
Class of Trade Restriction:	PO Receipt Cut off time:					
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Information Required to Process PO:	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?					