

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

						Introduction Ty	pe: Post Launch Change	е	x Final Version			Date:	7/12/	/2021
			PRODUCT INFORMAT	ΓΙΟΝ					SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application:							on: ANDA	a Temperatu	. Temperature – Indicate the USP temperature range for this product.					
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 040						7 (5)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	u. remperate		Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical		uo ro(n)(moa aorre							romporatoro rtango					
DUNS:	022490515								Other Temperature Range Re	equirement				
Proprietary Name (If Applicable) a		me: Meclizi	ine HCl Tablets						(write in)	Squirement				
Selling Unit NDC:	59746-122-06	inic.	Unit of Use NDC:			UPC:	3-59746-122-06-5		Notes					
UDI	001 10 122 00		CVX Code:			MVX Code:	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3		.10.00					
-											_			
Description:	Meclizine Hydroch	loride 12.5mg 100ct	lablet						Is this product to be shipped				No	
A ative la madiant/a).		Meclizine Hydrochlo	orido						Is this product to be shipped	to customers on a	iry ice?		No	
Active Ingredient(s):		weclizine riyurucino	onde					h Contact fo	r temperature excursion ques	etione:				
URL for Additional Product Inform	nation:	www.cadista.com	m/products/full-produc	+ liet				b. Contact to	Name:		Customer Se	nvice		
Address:	207 Kiley Drive	www.cauista.coi	in/products/run-produc	<u>t-list</u>	1	Address 2:			Number:		(800) 313-46			
City:	Salisbury				State:		Zip : 21801		Group E-mail:			customer.service@cadista.com		
Key Contact:	Jackie Emershaw	ershaw			Email:	Jackie.Emershav			Group E man.		customer.	SCI VICCIOCE	dista.com	
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646	<u>Te jubileoni</u>	c. Special red	gulations for product in any s	tates?			No	
Product Therapeutic Classificatio		Antinausea				(-,			Special returns requirements				No	
. round morapound diacomound					_				opecial returns requirements	Tor tino product.				
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	
The was dead in 0				Direct-Ship (Only			an otoro proc						
The product is? a legend device?			Is the Product	Neither	Only		100 count	e. Shelf life:	Protect product (unit of sale	e) from light?			No 0.4	
-		No	Is the Product	Neither		Size:	100 count	e. Shelf life:	belief at all titles at large at the				24	Months
if yes, enter class #		I	Orphan Drug Status				12.5mg		Initial shelf life at launch (if	airrerent):				Months
a product kit? if yes, list NDCs of		No	EDA Approval Status			Strength:	12.5mg			ORDER INFORM	ATION			
component parts			FDA Approval Status				TABLETS			ORDER IN ORM	ATION			
reverse numbered?		No				Dosage Form:	TABLE 13		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 10		unit.	
latex-free?		Yes	Allergens Fresent				Oval		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape	e:		Ampule		(vviite iii, e.	g. 1 DOX 01 1	, viais)	
correctional institution block?		Yes					Blue		Glass		Minimum o	der quantity	12	Yes
opioid?		No				Product Color	:		Tube			uo. qua,		100
Cannabinoid?		No	Country of Origin	US			TL 122		Vial Liquid Sql					
If Unit Dose, is item bar coded to u	unit dose for	110	,			Product Imprii	nt:		Vial Liquid Multi		If Yes, how	manv of whi	ich package t	tvpe?
hospital scanning?			Is this product covered u	nder the					Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (ΓAA)?	Yes				Vial Power Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS		•								
					Au		If Authorized Generic, other		PHA	RMACY ORDER	BILL UNIT			
I. Orange Book Rating:	AA				Au		If Authorized Generic, other section fields are not applicable	e Rec. sell unit	PHA	RMACY ORDER.		nit to pharm	icv:	
I. Orange Book Rating: II. Generic Equivalent to What Bra	AA and?:	Antivert			Au			Rec. Sell ullil		RMACY ORDER		nit to pharm	асу:	
		Antivert			Au			Rec. Sell ullil	t to customer?	RMACY ORDER	Rx billing u		асу:	
			Y CHAIN SECURITY ACT (I	DSCSA) INFOR				1 b	t to customer?	RMACY ORDER	Rx billing u	Each	асу:	
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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?: ition of manufactur	DRUG SUPPL	Yes No	DSCSA) INFOR	RMATION GLN: GCP:	0359746000004 0359746		1 b (Write-in, e.g	t to customer? oottle of 100 tablets . 1 Vial)	AND PACKING IN	Rx billing u X IFORMATION	Each Gram Milliliter		Saleable #
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Version 2021

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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 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



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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?					