

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

Version 2021	Introduction Type: Post Launch Change							nge	x Final Version			Date:	7/12/	2021	
			PRODUCT INFORMAT	TION					SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc.						Application	on: ANDA	a Temperat	a. Temperature – Indicate the USP temperature range for this product.						
					0659	7 (5) (1)	7.11571	a. remperat	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
Medical Device Class, if applical		uo ro(n)(moa ao mo	5 7.						romporatoro riango						
DUNS:	022490515				T T				Other Temperature Range R	equirement					
Proprietary Name (If Applicable) a		ne: Meclizir	ne HCl Tablets		1				(write in)	equirement.					
Selling Unit NDC:	59746-121-06	IC. IVICCIIZII	Unit of Use NDC:			UPC:	3-59746-121-06-8		Notes						
UDI	007 10 121 00		CVX Code:			MVX Code:	0 001 10 121 00 0		110100						
-											_				
Description:	Meclizine Hydrochio	oride 25mg 100ct Tal	DIET						Is this product to be shipped				No	1	
A ative Improvedient(a)		Meclizine Hydrochlor	vrido						Is this product to be shipped	to customers on a	iry ice?		No	I .	
Active Ingredient(s):	h Contact fo	b. Contact for temperature excursion questions:													
LIPI for Additional Product Inform	L for Additional Product Information: www.cadista.com/products/full-product-list							b. Contact it	Name: Customer Service						
Address:	207 Kiley Drive				1	Address 2:			Number:			(800) 313-4623			
City:	Salisbury				State:		Zip : 21801		Group E-mail:			customer.service@cadista.com			
Key Contact:	Jackie Emershaw	rshaw			Email:	Jackie.Emershav			0.0up =a		customer.	JCT VICC (49 CC	dista.com		
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646	TO JUDITOUTI	c. Special re	c. Special regulations for product in any states?				No	1	
Product Therapeutic Classification		Antinausea				(-,			Special returns requirements				No	1	
Trouble Thorapound Glacomound					1				opeoidi retarrio requirerrioria	o tot uno product.				I .	
	ADDITION	NAL PRODUCT INF	ORMATION			PRODUCT DE	ESCRIPTION INFORMATIO	d. Store pro	duct (unit of sale) upright?				No	1	
The was dead in 0				Direct-Ship ()nlv			ui oloio pio		(-) f l'b-0				i	
The product is? a legend device?	Г.		Is the Product	Neither	Jrily		100 count	e. Shelf life:	Protect product (unit of sal	le) from light?			No		
-	1	No	Is the Product	Neither		Size:	100 count	e. Sneif life:	legical at all the at lease to the				24	Months	
if yes, enter class #	1.		Orphan Drug Status				25mg		Initial shelf life at launch (i	r airrerent):				Months	
a product kit? if yes, list NDCs of	ļr	No	EDA Approval Status			Strength:	25HIg			ORDER INFORM	IATION				
component parts			FDA Approval Status				TABLETS			ORDER IN ORM	ATION				
reverse numbered?		No				Dosage Form:	: IABLE 13		Unit of Sale		What is the	NDC selling	unit?		
co-licensed?	_	No	Allergens Present						X Bottle		1 bottle of 1		unit.		
latex-free?	_	Yes	Allergens Fresent				Oval		Box/Carton			g. 1 Box of 1	0 Vials)		
preservative-free?		No				Product Shap	e:		Ampule		(vviite iii, e.	g. 1 Dox 01 1	5 viais)		
correctional institution block?		Yes					Blue		Glass		Minimum o	der quantity	12	Yes	
opioid?	-	No				Product Color	:		Tube			uci quantity		103	
Cannabinoid?	_	No	Country of Origin	US			TL 121		Vial Liquid Sql						
If Unit Dose, is item bar coded to		10	,g			Product Impri	nt:		Vial Liquid Multi		If Yes. how	many of wh	ich package t	type?	
hospital scanning?	u.ii. 0000 ioi		Is this product covered u	nder the					Vial Powder Sql		48	Each		.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	Yes				Vial Power Multi			Inner/Cartor	ı/Pack		
									Other: Write In			Case			
			FOR GENERIC DRUG PRO	DDUCTS											
					Au	thorized Generic	*If Authorized Generic, other	r	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	acction fields are not applied						Rec. sell uni	Rec. sell unit to customer?				Rx billing unit to pharmacy:			
II. Generic Equivalent to What Bra										1 bottle of 100 tablets			X Each		
		Antivert						1				Each			
		Antivert							bottle of 100 tablets			Each Gram			
			Y CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION			(Write-in, e.	bottle of 100 tablets						
		DRUG SUPPLY		DSCSA) INFOR					bottle of 100 tablets g. 1 Vial)		X	Gram Milliliter			
Does supplier meet DSCSA defini		DRUG SUPPLY	Yes	DSCSA) INFOR	RMATION GLN:	0359746000004			bottle of 100 tablets g. 1 Vial)	AND PACKING IN	X	Gram Milliliter			
Does supplier meet DSCSA defini Is product exempt from DSCSA?		DRUG SUPPLY		DSCSA) INFOR		0359746000004			bottle of 100 tablets g. 1 Vial)		X	Gram Milliliter			
		DRUG SUPPLY	Yes	DSCSA) INFOR		0359746000004			bottle of 100 tablets g. 1 Vial) ITEM		X	Gram Milliliter	Volume	Saleable #	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:		DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP:	0359746		(Write-in, e.g	bottle of 100 tablets g. 1 Vial)		X	Gram Milliliter	Volume (Cube)	Saleable # Pieces	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or	0359746			bottle of 100 tablets g. 1 Vial) ITEM	Dimensio	X NFORMATION ons (US msn	Gram Milliliter			
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributo	DRUG SUPPLY	Yes No No	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	0359746 riginal product		(Write-in, e.g	bottle of 100 tablets g. 1 Vial) ITEM Weight Lbs. 0.13	Dimensio Depth	X AFORMATION ons (US msn 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 Has FDA granted waiver/exceptio	s exclusive distribute	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	0359746 riginal product	repackaged product	(Write-in, e.g	bottle of 100 tablets g. 1 Vial) ITEM Weight Lbs. 0.13	Dimensio Depth	X AFORMATION ons (US msn Width	Gram Milliliter	(Cube)	Pieces	
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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	s exclusive distribute on/exemption for proo m FDA.	DRUG SUPPLY r? or? duct? GTIN	Yes No No No No No No And No No		GLN: GCP: If yes, was oi purchased di Provide sour	0359746 riginal product irect from mfr?		Item/Each: Box/Carton/Inner Pack: Case: Pallet:	bottle of 100 tablets g. 1 Vial) ITEM Weight Lbs. 0.13 Bundle/	Dimension Depth 1.9	X IFORMATION Ons (US msn Width 1.9	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 Box/Carton/Bundle/Inner Pack X Case	s exclusive distribute on/exemption for proo m FDA.	DRUG SUPPLY r? or? duct? GTIN leable Quantity 1 48	Yes No No No No No HAND HIBCC PRODUCT IN	IFORMATION	GLN: GCP: If yes, was or purchased di Provide sour	0359746 riginal product riect from mfr? ce manufacturer for N-14 59746121068 59746121066		Item/Each: Box/Carton/Inner Pack: Case: Pallet: Regular Cos Invoice Cost As of date:	Weight Lbs. 0.13 Bundle/ 6.85 COST INFORMATION It t (WAC) (\$)	Dimension Depth 1.9 15.25	X IFORMATION Ons (US msn Width 1.9 11.5 Vendor #: Whsl. Code	Gram Milliliter N Ints.) Height 4 5 WHOLESAL #:	(Cube) 14.44 0.00 876.88 0.00	1 48	



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



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:	Overnight receipt available:					
Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	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?					