

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

Version 2021						Introduction Ty	ype: Post Lau	nch Change		x Final Version			Date:	6/9/2	2023			
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*	*				
Company Name: Jubilant Cadista Pharmaceuticals Inc. ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.											
Application Number for NDA/AN				040	0659					nperature Range	Controlled Room		and 25 C (68	° – 77° F)				
Medical Device Class, if applical																		
DUNS:	022490515								Oth	er Temperature Range I	Requirement							
Proprietary Name (If Applicable) a	and Established N	lame: Mecl	lizine HCI Tablets						[(write in)								
Selling Unit NDC:	59746-122-10		Unit of Use NDC:				3-59746-122-10-2		Not	es								
UDI			CVX Code:			MVX Code:												
Description:	Meclizine Hydroc	chloride 12.5mg 1000	0ct Tablet							nis product to be shipped				No]			
Is this product to be shipped to customers on dry ice? No]								
Active Ingredient(s): Meclizine Hydrochloride																		
URL for Additional Product Information: www.cadista.com/products/full-product-list								b. Contact for temperature excursion questions: Name: Customer Service										
Address:	207 Kiley Drive	www.cadista.c	om/products/full-product	<u>t-list</u>	1	Address 2:				ne: nber:		(800) 313-46						
City:	Salisbury				State:	MD	Zip: 21801			oup E-mail:			service@ca	dista com				
Key Contact:	Customer Service	e			Email:		ce@cadista.com					<u>customer</u> .	<u>service e</u> co	uista.com				
Phone Number:	(800) 313-4623				Fax:	N/A	<u> </u>		c. Special regulati	ons for product in any	states?			No	1			
Product Therapeutic Classificatio	n:	Antinausea			1					cial returns requirement				No	1			
															1			
	ADDIT	IONAL PRODUCT I				PRODUCT D	ESCRIPTION INFO	RMATION	d. Store product (unit of sale) upright? No]			
The product is?			Is the Product	Direct-Ship C	Inly				Pro	tect product (unit of sa	ale) from light?			No	1			
a legend device?		No	Is the Product	Neither		Sizo	1000 count		e. Shelf life:					24	Months			
if yes, enter class #			Orphan Drug Status			Size:				ial shelf life at launch (if different):				Months			
a product kit?		No				Strength:	12.5mg											
if yes, list NDCs of			FDA Approval Status			ouoligui					ORDER INFOR	MATION						
component parts						Dosage Form	: TABLETS					M/hat is the	NDC selling					
reverse numbered?		No	Allergens Present							t of Sale X Bottle		1 bottle of 1		unit?				
co-licensed? latex-free?		No Yes	Allergens Fresent				Oval			Box/Carton			g. 1 Box of 1) Vials)				
preservative-free?		No				Product Shap	e:			Ampule		(White iii, c.	g. 1 Dox 01 1	5 viai3)				
correctional institution block?		Yes				Desident Only	Blue			Glass		Minimum o	rder quantity	?	Yes			
opioid?		No				Product Colo	r:			Tube								
Cannabinoid?		No	Country of Origin	US		Product Impri	TL 122			Vial Liquid Sgl								
If Unit Dose, is item bar coded to u	unit dose for					outlot impli				Vial Liquid Multi				ch package	type?			
hospital scanning?			Is this product covered u Trade Agreements Act (Mar					Vial Powder Sql		12	Each	(De ele				
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	Yes					Vial Power Multi Other: Write In			Inner/Carton Case	/Раск				
			FOR GENERIC DRUG PR	ODUCTS						Other: Write III		_	Case					
			TOR GENERIC DRUGTR	000013														
					Au	uthorized Generic	*If Authorized Gene	ric, other		PH	IARMACY ORDER	R / BILL UNIT						
I. Orange Book Rating:	AA				I		section fields are no		Rec. sell unit to c	ustomer?		Ry billing u	nit to pharma	acv.				
II. Generic Equivalent to What Brand?: Antivert®						1 bottle of 1000 tablets				X Each								
				(Write-in, e.g. 1 Vial)			-	Gram										
		DRUG SUP	PLY CHAIN SECURITY ACT (DSCSA) INFOR	MATION								Milliliter					
Does supplier meet DSCSA defini	tion of manufactu	urer?	Yes	_	GLN:	0359746000004				ITEN	I AND PACKING I	NFORMATIO	N					
Is product exempt from DSCSA?			No															
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ions (US msn	-	Volume	Saleable #			
Other exemption - Write in:			Νο								Depth	Width	Height	(Cube)	Pieces			
Is product repackaged? Is product sold by manufacturer's	avaluaius distrik		No	_	If yes, was of direct from n	riginal product purc	hased		Item/Each:	0.33	2.4	2.4	5.08	29.26	1			
Has FDA granted waiver/exception			No	_		ce manufacturer for	repackaged produ	ict	Box/Carton/Bund	o/								
If yes, attach documentation from					Trovide Sour		repackagea produ	iot	Inner Pack:					0.00				
									Case:	4.42	10.25	7.75	5.40	407.54	10			
		G	TIN AND HIBCC PRODUCT II	NFORMATION						4.42	10.25	7.75	5.13	407.51	12			
									Pallet:					0.00				
Saleable Unit of Measure	:	Saleable Quantity	HIBCC			IN-14	Unit of Use	GTIN-14						0.00				
	X Item/Each 1 00359746122102																	
Box/Cator/Bundle/Inner Pack 40359746 X Case 12				59746122100	46122100		COST INFORMATION			WHOLESALER USE ONLY:								
Pallet		12			403	009740122100			Regular Cost			Vendor #:						
1 cirics									Invoice Cost (WA	C) (\$)	\$171.78	Whsl. Code	#:					
	1									- / /	φ171.70	Fineline Co						
					1				As of date:									
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza													
*Please provide any additional inf	ormation on page	e 2.				See new p. 3 for I	Designated Drop SI	hip Only.	Sig	*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:								

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

Version 2021 Fo	or Designated Drop Ship Only Products, Please Use Page 3
MAT	FERIAL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	No SDS Hazard Classification No Organic Corrosive No Inorganic Oxidizer No Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No No NFPA Storage Level: Image: Contact Hazard
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which: Hazardous Waste Identification Image: No EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity	No REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? No Website URL: No No Med Guide Required Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) No REMS: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned DEA #:
Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP# ADD'L STORAGE INFORMATION	by Supplier: NPI #: Comments
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION: No CLASS OF TRADE RESTRICTION:	No RETURN INSTRUCTIONS No Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:
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:	Yes Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? SCELLANEOUS 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: Image: Comparison of the co
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: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?