

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

Version 2024						Introduction Typ	be:		Final Version			Date:	2/24	/2025
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: Jubilant Cadista Pharmaceuticals Inc. ANDA						a. Temperature	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	DA/BLA; PMA/510	k): 04	0268			NDA 505(b) Type:	NOT APPLICABLE		emperature Range	Controlled Room		and 25 C (68	8° – 77° F)	
Medical Device Class, if applicab	ole:													
DUNS:	118694141							C	ther Temperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Pr	ochlorperazine Maleate Tablets						(write in)					
Selling Unit NDC:	59746-113-06		Unit of Use NDC:				-59746-113-06-3	N	otes					
UDI			CVX Code:			MVX Code:								
Description:	Prochlorperazine I	Maleate 5mg 100) Tablets						this product to be shippe				No	
		Development						Is	this product to be shippe	ed to customers on o	dry ice?		No	
Active Ingredient(s): Prochlorperazine Maleate							b Contact for to	b. Contact for temperature excursion questions:						
URL for Additional Product Inform	nation:	www.cadista	.com/products/full-product-l	ist					ame:	uestions.	Customer S	ervice		
Address:	790 Township Line			<u>150</u>		Address 2: S	Suite 325		umber:		(800) 313-4			
City:	Yardley				State: PA Zip: 19067							customer.service@cadista.com		
Key Contact:	Customer Service				Email:	customer.service	e@cadista.com							_
Phone Number:	(800) 313-4623				Fax:	N/A			ations for product in any				No	_
Product Therapeutic Classification	n:	Antiemetic ; An	tipsychotic					S	pecial returns requiremen	nts for this product?			No	
														-
	ADDITIC	DNAL PRODUC	T INFORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store produc	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly				rotect product (unit of s	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100 count	e. Shelf life:					24	Months
if yes, enter class # a product kit?		N	Orphan Drug Status			1	Ema		itial shelf life at launch	(If different):				Months
if yes, list NDCs of		No	FDA Approval Status			Strength:	5mg			ORDER INFORM				
component parts			T DA Approval Status				TABLETS			ORDER IN OR				
reverse numbered?		No				Dosage Form:		u	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 1			
latex-free?		Yes	_			Product Shape	Round		Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
preservative-free?		No				i roudet onape			Ampule					
correctional institution block?		Yes				Product Color:	Chartreuse		Glass		Minimum o	rder quantity	?	Yes
opioid?		No		US			TI 440	- 11 -	Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	unit alaana faa	No	Country of Origin	05		Product Imprin	t: TL 113 scorred on one side/ plain on other		Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of wh	ioh nookogo	turno?
hospital scanning?	init dose for		Is this product covered und	ler the			ono oldo, plan on onoi		Vial Powder Sql		48	Each	сп раскауе	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA		Yes				Vial Power Multi		10	Inner/Cartor	/Pack	
									Other: Write In			Case		
•			FOR GENERIC DRUG PRO	OUCTS		•						_		
					x Au		If Authorized Generic, other		PI	HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					S	ection fields are not applicable	Rec. sell unit to	Rec. sell unit to customer?			Rx billing unit to pharmacy:		
II. Generic Equivalent to What Bran	nd?:	Compazine®							e of 100 tablets		Х	Each		
								(Write-in, e.g. 1	√ial)			Gram		
		DRUG SU	IPPLY CHAIN SECURITY ACT (D	SCSA) INFOR	MATION			HCPCS J-Code:				Milliliter		
Does supplier meet DSCSA definit	tion of manufactur	er?	Yes		GLN:	0359746000004			ITE	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No		OLIN.	00007 40000004								
If yes, select exemption:					GCP:	0359746				Dimone	ions (US msr	nte)	Volume	Saleable #
Other exemption - Write in:					GCF.	0333740			Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	iginal product purch	ased	Item/Each:	0.40					
Is product sold by manufacturer's	exclusive distribu	tor?	No		direct from m				0.13	1.9	1.9	4	14.44	1
Has FDA granted waiver/exception	n/exemption for pro	oduct?	No		Provide source	ce manufacturer for r	epackaged product	Box/Carton/Bun	dle/				0.00	
If yes, attach documentation from	n FDA.							Inner Pack:					0.00	
			GTIN AND HIBCC PRODUCT INF	OPMATION				Case:	6.39	15.5	11.75	5.25	956.16	48
			GHN AND HIBCC PRODUCT INF	ORMATION				Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GTIN-14	Fallet.					0	
	tti ib tag(1/14)	Quantity	11200		011									
X Item/Each	N	1			003	59746113063								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	_Y:
X Case	N	48			403	59746113061								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (W	AC) (\$)	\$34.88	Whsl. Code			
								As of date:	2/24/2025		Fineline Co	ae:		
								As of date.	2127/2023					
		0												
μ			Attach copy of SAFETY DAT	A SHEET (SD	S) or non haza	rd letter, PACKAGE IN	ISERT, LABEL AND PHOTO C	F PRODUCT PACKAG	NG and BARCODE.		1			
1	ormation on nage ?	2	A MACH SOPY OF ONE ETT DAT		-, oon nuza		esignated Drop Ship Only.		ignature:					
*Please provide any additional info									• · · · · · · ·					

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

Version 2024 For Designated Drop Ship Only Products, Please Use Page 3									
MATERIAL H	AZARD 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? No C. Contact Hazard	SDS Hazard Classification Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard Does the product have an Aerosol class? If yes, identify No NFPA Storage Level: Image Level: NFPA Storage Level: Image Level: Is the product a NIOSH hazardous drug? No If yes, indicate which: Image Level:								
b. Proper Shipping Name c. DOT Hazard Class	Hazardous Waste Identification								
d. Packing Group									
e. Inhalation Hazard? 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	REMS or REGISTRY RESTRICTIONS								
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:								
Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo	Med Guide Required No Limited Distribution Requirement No Comments / Details: (For example, iPledge program?)								
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 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);	REMS: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:								
SP#	Registry:								
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments								
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS								
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: Is product returnable for credit:								
	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: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?								
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:								



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

Version 2024 FC	OR DESIGNATED DROP SHIP PRODUCT ONLY - if	not a designated drop ship, do not complete.	
Order Method for Design	ated 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:	Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hour Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:	urs Days
Expedited Freight Charges or Otl	her 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: Priority Overnight receipt available:	Monday Tuesday Wednesday Thursday Friday
Class of Trade	- Restriction:	PO Receipt Cut off time:	
No restriction: Select YES if sold to retail pharmacy, he Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices onl Restricted from US territories? (explain in comments) Comments:	ospitals, clinics and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time:	ne #:
Other Data Information F	Required to Process PO:	Return Instruction	S
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product If so, which states? Other requirements? Comments?	ct in certain states?
Miscellaneo	bus Notes:		
		ADDITIONAL INFORMA Is product order for scheduled patient procedure? Is product order for restocking purposes?	