

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

Version 2021						Introduction Ty	ype: Po	st Launch Change	]	x Fi	inal Version			Date:	6/9/	2023	
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*										
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.											
Application Number for NDA/AN			:e):	040	268					Temperatur		Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applica	able:																
DUNS:	022490515										perature Range	Requirement					
Proprietary Name (If Applicable)		ame: Prochl	orperazine Maleate Tablets							(write	in)						
Selling Unit NDC: UDI	59746-115-06		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-59746-115	-06-7	-	Notes							
						INVA Code.			1								
Description:	Prochlorperazine	Maleate 10mg 100 Ta	ablets									d to customers on i			No No		
Active Ingredient(s):		Prochlorperazine M	aleate						+	is this prodi	uct to be snippe	u to customers on t	ary ice?		INO		
Active ingredient(s): Procniorperazine maleate					b. Contact fo	r temperatur	e excursion qu	estions:									
URL for Additional Product Inform	mation:	www.cadista.com	m/products/full-product	-list						Name:			Customer S	ervice			
Address:	207 Kiley Drive					Address 2:				Number:							
City:	Salisbury		State:			MD	<b>Zip</b> : 2180		Group E-mail:			<u>customer.service@cadista.com</u>					
Key Contact: Phone Number:	(800) 313-4623	9			Email: Fax:	customer.service	ce@cadista	<u>.com</u>	a Cuanial sa						Na	ı	
Product Therapeutic Classification		Antiemetic ; Antipsy	vahatia		rax:	IN/A			c. Special reg	-	product in any	states? ts for this product?			No No		
Product Therapeutic Classification	on:	Antiemetic , Antipsy	CHOLIC							Special reli	urns requiremen	is for this product?			INO		
	ADDIT	IONAL PRODUCT IN	FORMATION			PRODUCT D	ESCRIPTION	NINFORMATION	d Store prod	duct (unit of s	sale) upright?				No		
The product is?	7,5511		Is the Product	Direct-Ship O	nlv	1 1105001 5		5	u. otore proc	-		ale) from light?			No		
a legend device?		No	Is the Product	Neither	illy		100 cd	ount	e. Shelf life:	Protect pro	oduct (unit of Sa	ale) from light?			24	Months	
if yes, enter class #		INO	Orphan Drug Status			Size:	100 00	ount	c. onen me.	Initial shelf	f life at launch (	if different):				Months	
a product kit?		No				Ctuan mth.	10mg										
if yes, list NDCs of			FDA Approval Status			Strength:						ORDER INFOR	MATION				
component parts						Dosage Form	: TABLI	ETS									
reverse numbered?		No	All							Unit of Sale				NDC selling	unit?		
co-licensed?		No Yes	Allergens Present				Round	4			ottle ox/Carton		1 bottle of 1	oo tablets .g. 1 Box of 1	0 Viale)		
preservative-free?		No				Product Shap	e:				mpule		(vviite-iii, e	.g. 1 D0x 01 1	o viais)		
correctional institution block?	•	Yes				Described Color	Chartr	reuse			lass		Minimum o	rder quantity	y?	Yes	
opioid?		No				Product Color	r:				ube						
Cannabinoid?		No	Country of Origin	US		Product Impri	int: TL 11	5	Vial Liquid Sgl								
If Unit Dose, is item bar coded to	unit dose for					. roudet impri					ial Liquid Multi				ich package	type?	
hospital scanning?			Is this product covered u		Vaa						ial Powder Sql		48	Each	-/Deals		
If Unit Dose, indicate NDC here:  Trade Agreements Act (TAA)?  Yes					Vial Power Multi Inner/Carton/Pack Other: Write In Case												
FOR GENERIC DRUG PRODUCTS																	
				3200.0													
					Au	thorized Generic	*If Authorized	d Generic, other	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	and the fields are not and			are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:												
II. Generic Equivalent to What Bra		Compazine®							1 b	oottle of 100 ta	ablets		X	Each	,-		
-									(Write-in, e.g	j. 1 Vial)		_		Gram			
		DRUG SUPPL	Y CHAIN SECURITY ACT (	DSCSA) INFOR	MATION									Milliliter			
Dana sumulian maat DCCCA dafin			Von	7	CLN.	0250746000004					ITEM	AND PACKING I	NEODMATIO	N			
Does supplier meet DSCSA defin Is product exempt from DSCSA?		lei :	Yes No	-	GLN:	0359746000004					115	AND PACKING I	NI-OKWATIO	N-			
i i					GCP:	0359746			1			Dimone	ions (US msr	nte \	Valuma	Calaabla#	
If yes, select exemption: Other exemption - Write in:					GCP:	0359746			J		Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?			No		If ves. was or	riginal product purcl	hased		Item/Each:			1			_ ` _ <i></i>		
Is product sold by manufacturer's	's exclusive distrib	utor?	No		direct from m						0.11	1.9	1.9	4	14.44	1	
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer for	repackaged	product	Box/Carton/E	Bundle/					0.00		
If yes, attach documentation fro	om FDA.								Inner Pack:						0.00		
		CTI	N AND HIBCC PRODUCT II	IFORMATION					Case:		6.14	15.5	11.75	5.25	956.16	48	
		GII	N AND RIBCC PRODUCT IF	FORMATION					Pallet:								
Saleable Unit of Measure		2-1	HIBCC		GTI	N-14	Unit	of Use GTIN-14	r anet.						0.00		
	:					59746115067						1					
X Item/Each	;	Saleable Quantity 1		Box/Carton/Bundle/Inner Pack							COST INFORMATION WHOLESALER USE ONLY:						
X Item/Each Box/Carton/Bundle/Inner Pack	\$	1								60311	NEURMATION			WHOLESAL			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	:				403	59746115065					NFORMATION			WHOLESAL			
X Item/Each Box/Carton/Bundle/Inner Pack	,	1			403	59746115065			Regular Cost	t	NFORMATION		Vendor #:				
X Item/Each Box/Carton/Bundle/Inner Pack X Case		1			403	59746115065			Regular Cost	t	NFORMATION	\$52.32	Whsl. Code	· #:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case		1			403	59746115065			Invoice Cost	t	NPORMATION	\$52.32		· #:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case		1			403	59746115065				t	NPORMATION	\$52.32	Whsl. Code	· #:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	•	1			403	59746115065			Invoice Cost	t	NFORMATION	\$52.32	Whsl. Code	· #:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case		1	Attach copy of SAFETY DA	TA SHEET (SD			INSERT, LAB	SEL AND PHOTO OF F	As of date:	t (WAC) (\$)		\$52.32	Whsl. Code	· #:			



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

#### Version 2021

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?	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?						
Is the product a CA Prop 65 carcinogen?  No	Organic Corrosive Inorganic Oxidizer					
Is the product a CA Prop 65 reproductive toxicant?  Does the product label bear a CA Prop 65 warning?  No	Inorganic Oxidizer Steroid/Androgen Contact Hazard					
boes the product label bear a OATTOP to warning:	Ornaci Tazard					
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No					
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:					
(If yes, attach SDS with special instructions.)	NFPA Storage Level:					
e. Does the product contain DEHP?						
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?					
(if yes, answer a-e below and provide SDS)	If yes, indicate which:					
a. UN/Identification Number b. Proper Shipping Name						
c. DOT Hazard Class	Hazardous Waste Identification					
d. Packing Group						
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA?						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number						
b. Proper Shipping Name	Is there a REMS on this product?					
c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry?  Website URL:					
e. Inhalation Hazard?	Website ORL.					
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? No	REMS:					
RQ Threshold:	REMS Program Manager Name: Phone:					
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:					
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:					
No (if yes, identify method below)  Limited Quantity	Provider Name: DEA #: Site Enrollment Number assigned NCPDP#:					
Consumer Commodity, ORM-D	by Supplier: NPI #:					
Small Quantity (49 CFR 173.4)						
Special Permit; DOT-SP	Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);						
SP#	Registry:					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:					
	Comments					
Is the Product Controlled Substance 2	RETURN INSTRUCTIONS					
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	KETORI NOTIONS					
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:	Consider outletions or returns continued for this					
Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?					
Comments:						
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:					
- INIGCLELAT						



## **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 S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:		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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
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 in certain states?  If so, which states? Other requirements? Comments?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?