

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

					Introduction Type:			Final Version			Date:	2,2 11	2025
		PRODUCT INFORMATION						SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Jubilant Cadista	Pharmaceuticals Inc.				Application:	ANDA	a. Temperature - Indica	ate the USP tempe	rature range for th	is product.			
Application Number for NDA/ANDA/BLA; PMA/51				N	IDA 505(b) Type:	NOT APPLICABLE	-	ture Range	Controlled Room -		and 25 C (68	' – 77° F)	
Medical Device Class, if applicable:											`		
DUNS: 118694141							Other Te	mperature Range F	Requirement				
Proprietary Name (If Applicable) and Established N	ame: Prochlorg	perazine Maleate Tablets						ite in)					
Selling Unit NDC: 59746-115-06		Unit of Use NDC:			UPC: 3-59	746-115-06-7	Notes						
UDI		CVX Code:			MVX Code:		1						
Description: Prochlorperazine Maleate 10mg 100 Tablets								aduat ta ba abinnaa	I to customers on ic	-02		No	1
Production and a second									to customers on d			No	
Active Ingredient(s): Prochlorperazine Maleate							oddot to bo omppoo	i to odotomoro on d	.,				
							b. Contact for temperat	b. Contact for temperature excursion questions:					
URL for Additional Product Information:	Additional Product Information: www.cadista.com/products/full-product-list						Name:	·		Customer Se	rvice		
Address: 790 Township Li				Address 2: Suite 325			Number:	:		(800) 313-46	23		
City: Yardley					State: PA Zip: 19067			-mail:		customer.s	ervice@ca	dista.com	
Key Contact: Customer Service Email													
Phone Number: (800) 313-4623			Fax	c: [N/A		c. Special regulations f					No	
Product Therapeutic Classification:	Antiemetic ; Antipsycho	otic					Special re	eturns requirement	s for this product?			No	
ADDIT	IONAL PRODUCT INFO	RMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit o	of sale) upright?				No	
The product is?			ct-Ship Only				Protect p	product (unit of sa	le) from light?			No	
a legend device?	1.10	Is the Product Neith	ier		Size:	100 count	e. Shelf life:					24	Months
if yes, enter class #		Orphan Drug Status					Initial sh	elf life at launch (i	f different):				Months
a product kit?	No				Strength:	10mg			ODDED INCODE	ATION			
if yes, list NDCs of component parts		FDA Approval Status				TABLETS			ORDER INFORM	ATION			
reverse numbered?	No				Dosage Form:	TABLETS	Unit of S	alo		What is the	NDC salling	unit?	
co-licensed?		Allergens Present						Bottle		1 bottle of 10			
latex-free?	Yes	Allergens i resent				Round		Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?	No				Product Shape:			Ampule		,,		,	
correctional institution block?	Yes			_	Deadwat Calan	Chartreuse		Glass		Minimum or	der quantity	?	Yes
opioid?	No				Product Color:			Tube				,	
Cannabinoid?	No	Country of Origin US			Product Imprint:	TL 115 scorred on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unit dose for					. roudot imprima	side/ plain on other		Vial Liquid Multi			•	ch package t	type?
hospital scanning?		Is this product covered under the		,				Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	Yes					Vial Power Multi			Inner/Carton	Pack	
L								Other: Write In			Case		
	F	FOR GENERIC DRUG PRODUCT	S										
				7 A.usha	orized Generic *If A	uthorized Generic, other		DLI	ARMACY ORDER	/ BILL LINIT			
				Autho	onzed Generic III Al	on fields are not applicable			ARMACT ORDER	BILL ONIT			
					secti							cy:	
I. Orange Book Rating: AB					secti	on neids are not applicable	Rec. sell unit to custom		1	Rx billing ur			
I. Orange Book Rating: II. Generic Equivalent to What Brand?:	Compazine®				secti	on neids are not applicable	1 bottle of 100			Rx billing ur X	Each		
		CHAIN SECURITY ACT (DSCSA) INFORMATION		secti	on neids are not applicable	1 bottle of 100 (Write-in, e.g. 1 Vial)				Each Gram		
		CHAIN SECURITY ACT (DSCSA) INFORMATION		secti	on notes are not applicable	1 bottle of 100]		Each		
II. Generic Equivalent to What Brand?:	DRUG SUPPLY (CHAIN SECURITY ACT (DSCSA	A) INFORMATION GLN:		secti	or new applicable	1 bottle of 100 (Write-in, e.g. 1 Vial)	0 tablets	AND PACKING IN	X	Each Gram Milliliter		
	DRUG SUPPLY ((or new applicable	1 bottle of 100 (Write-in, e.g. 1 Vial)	0 tablets	AND PACKING IN	X	Each Gram Milliliter		
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA?	DRUG SUPPLY (Yes	GLN:		0359746000004	от поло вто тох аррикавае	1 bottle of 100 (Write-in, e.g. 1 Vial)	0 tablets		X	Each Gram Milliliter	Volume	Saleable #
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption:	DRUG SUPPLY (Yes				от посто спот арриматис	1 bottle of 100 (Write-in, e.g. 1 Vial)	0 tablets	Dimensio	X IFORMATION ons (US msm	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	DRUG SUPPLY (Yes	GLN:	(0359746000004		1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code:	0 tablets ITEM Weight Lbs.	Dimensio Depth	X IFORMATION Ons (US msm Width	Each Gram Milliliter its.) Height	(Cube)	Pieces
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption:	DRUG SUPPLY (Yes No	GLN:	as origi	0359746000004 0359746 inal product purchase		1 bottle of 100 (Write-in, e.g. 1 Vial)	0 tablets	Dimensio	X IFORMATION ons (US msm	Each Gram Milliliter		
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacts is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	DRUG SUPPLY (Yes No	GLN: GCP: If yes, we direct from	as origi om mfr?	0359746000004 0359746 inal product purchase	d	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/	0 tablets ITEM Weight Lbs.	Dimensio Depth	X IFORMATION Ons (US msm Width	Each Gram Milliliter its.) Height	(Cube) 14.44	Pieces
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distribution.	DRUG SUPPLY (Yes No No	GLN: GCP: If yes, we direct from	as origi om mfr?	0359746000004 0359746 inal product purchase ?	d	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code:	0 tablets ITEM Weight Lbs.	Dimensio Depth	X IFORMATION Ons (US msm Width	Each Gram Milliliter its.) Height	(Cube)	Pieces
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distributed in the product sold by manufacturer is exclusive distributed.	DRUG SUPPLY (urer? puttor? product?	Yes No No No No	GLN: GCP: If yes, widirect fro	as origi om mfr?	0359746000004 0359746 inal product purchase ?	d	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/	Utablets ITEM Weight Lbs. 0.16	Dimension Depth 1.9	X IFORMATION Ons (US msm Width 1.9	Each Gram Milliliter Its.) Height 4	(Cube) 14.44 0.00	Pieces 1
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distributed in the product sold by the product sold by manufacturer's exclusive distributed in the product sold by the prod	DRUG SUPPLY (urer? puttor? product?	Yes No No	GLN: GCP: If yes, widirect fro	as origi om mfr?	0359746000004 0359746 inal product purchase ?	d	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	0 tablets ITEM Weight Lbs.	Dimensio Depth	X IFORMATION Ons (US msm Width	Each Gram Milliliter its.) Height	(Cube) 14.44	Pieces
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II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distributed in the selection of the	DRUG SUPPLY (urer? putor? product? GTIN A Saleable Quantity	No No No No No No No No	GLN: GCP: If yes, widirect fro	as origi om mfr? source	0359746000004 0359746 inal product purchase? manufacturer for repa	d	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	Utablets ITEM Weight Lbs. 0.16	Dimension Depth 1.9	X IFORMATION Ons (US msm Width 1.9	Each Gram Milliliter Its.) Height 4	(Cube) 14.44 0.00 956.16	Pieces 1
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II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacts is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distribles that FDA granted waiver/exception/exemption for product sold by manufacturer's exclusive distribles FDA granted waiver/exception/exemption for product sold by manufacturer's exclusive distribles FDA granted waiver/exception/exemption for product sold by manufacturer's exclusive distributions. Saleable Unit of Measure RFID tag(Y/N) X Item/Each Box/Carton/Bundle/Inner Pack X Case	DRUG SUPPLY (urer? buttor? oroduct? GTIN A Saleable Quantity 1	No No No No No No No No	GLN: GCP: If yes, widirect fro	as origi om mfr? source	0359746000004 0359746 inal product purchase? manufacturer for repa	d	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.16 6.39	Dimensic Depth 1.9	X IFORMATION ons (US msm Width 1.9	Each Gram Milliliter tts.) Height 4 5.25	(Cube) 14.44 0.00 956.16 0	1 48
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II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distribured in the selection of the	DRUG SUPPLY (urer? GTIN A Saleable Quantity 1 48	No No No No No No HIBCC PRODUCT INFORM	GLN: GCP: If yes, with direct from Provide station	as origiom mfr? source GTIN-1 003597	0359746000004 0359746 inal product purchase? manufacturer for repair 14 746115067 746115065	d Lockaged product Unit of Use GTIN-14	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: COST Regular Cost Invoice Cost (WAC) (\$) As of date:	### O tablets ### Weight Lbs. 0.16 6.39 TINFORMATION 2/24/2025	Dimensic Depth 1.9	X IFORMATION ons (US msm Width 1.9 11.75	Each Gram Milliliter Its.) Height 4 5.25	(Cube) 14.44 0.00 956.16	1 48
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manufacture is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distribured in the selection of the	DRUG SUPPLY (urer? GTIN A Saleable Quantity 1 48 48	No No No No No No No No	GLN: GCP: If yes, with direct from Provide station	as origiom mfr? source GTIN-1 00359: 40359:	0359746000004 0359746 inal product purchase? manufacturer for repair 14 746115067 746115065	d Lockaged product Unit of Use GTIN-14	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: COST Regular Cost Invoice Cost (WAC) (\$) As of date:	Weight Lbs. 0.16 6.39 TINFORMATION 2/24/2025	Dimensic Depth 1.9	X IFORMATION ons (US msm Width 1.9 11.75	Each Gram Milliliter Its.) Height 4 5.25	(Cube) 14.44 0.00 956.16	1 48



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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): SDS Hazard Classification a. Cytotoxic? No 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? Oxidizer No Inorganic 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 No 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)

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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					
	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?					