

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

Version 2021						Introduction 7	Туре:	New Item		Х	Final Version			Date:	6/17	/2024
			PRODUCT INFORMA	ΓΙΟΝ							SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 211320 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applicable:																
DUNS:	022490515								_		mperature Range R	Requirement				
Proprietary Name (If Applicable) a		lame: Chlorti	halidone Tablets						-		ite in)					
Selling Unit NDC: UDI	59746-760-01		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-5974	46-760-01-4	+	Notes						
			CVA Code.			WVX Code.			1							
Description:	Chlorthalidone 2	5mg 100ct Tablets									oduct to be shipped				No	-
Active Ingredient(s): Is this product to be shipped to customers on dry ice? No																
								b. Contact fo	r temperat	ture excursion que	estions:					
URL for Additional Product Inform	nation:	www.cadista.coi	m/products/full-product	-list					Î	Name:			Customer S			
Address:	790 Township Lir	ne Road				Address 2:	Suite 3			Number			(800) 313-46			
City:				State:	PA		19067	Group E-mail:				customer.service@cadista.com				
Key Contact: Phone Number:					Email: Fax:	customer.service@cadista.com N/A			c. Special regulations for product in any states?					No	1	
Product Therapeutic Classification		Oral Hypertensive			ı ax.	IV/A			c. Special re	-	eturns requirements				No	-
Froduct Therapeutic Classification	л.	Ciai riyperterisive								Special i	eturns requirement	s for trits product?			INU	
	ADDIT	IONAL PRODUCT IN	FORMATION			PRODUCT	DESCR	IPTION INFORMATION	d. Store prod	duct (unit d	of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nlv				1		product (unit of sa	la) from light?			No	1
a legend device?		No	Is the Product	Neither	,			100 count	e. Shelf life:	riotecti	product (unit or sa	ie) iroin light:			36	Months
if yes, enter class #		110	Orphan Drug Status			Size:		100 oount	l cronon mor	Initial sh	elf life at launch (i	f different):				Months
a product kit?		No				Strength:		25mg			•					-
if yes, list NDCs of			FDA Approval Status			ou engui.						ORDER INFORM	MATION			
component parts		1				Dosage For	m:	Tablet					140	NDOIII		
reverse numbered? co-licensed?		No	Allergens Bresent							Unit of S	Bottle		1 Bottle of 1	NDC selling	unit?	
latex-free?		Yes Yes	Allergens Present					Flat Round Tablet			Box/Carton			.g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Sha	ape:	riat Round Tablet			Ampule		(vviite iii, e.	g. I Dox of I	o viais)	
correctional institution block?		Yes				Product Col		Light Yellow			Glass		Minimum o	rder quantity	y?	Yes
opioid?		No				Product Col	or:				Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	orint:	'103'			Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		In this was dead account to	a da a tha							Vial Liquid Multi				ich package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		No						Vial Powder Sql Vial Power Multi		24	Each Inner/Carton	n/Pack	
Il Offit Dose, indicate NDC here.			Trade Agreements Act (1	AA):	INU						Other: Write In			Case	I/FdUK	
			FOR GENERIC DRUG PR	ODUCTS					1		,			1		
					Αι	thorized Generic		thorized Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating: AB					section fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:					
II. Generic Equivalent to What Bra	and?:	Hygroton®								Bottle of 10	0 tablets		Х	Each		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Write-in, e.g. 1 Vial)							Gram									
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION									Milliliter		
Does supplier meet DSCSA defin	ition of manufactu	ırar?	Yes	7	GLN:	8904184010027					ITEM	AND PACKING II	NEORMATIO	N		
Is product exempt from DSCSA?			No	-	OLIV.	0304104010027						7.1.1.2 1 71.3.1.1.1.3.1.				
								Saleable #								
Other exemption - Write in:					GOF.	0339740			1		Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was o	riginal product pur	chased		Item/Each:		0.07	1.54	1.54	3.35	7.94	1
Is product sold by manufacturer's			No		direct from n	nfr?					0.07	1.54	1.54	3.35	7.94	'
Has FDA granted waiver/exception		product?	No		Provide sour	ce manufacturer fo	or repac	kaged product	Box/Carton/l	Bundle/					0.00	
If yes, attach documentation fro	m FDA.								Inner Pack:							
		GTI	N AND HIBCC PRODUCT II	JEORMATION					Case:		2.61	9.45	6.5	4.33	265.97	24
		011	IN AND HIBCC PRODUCT II	II OKWATION					Pallet:							
Saleable Unit of Measure	:	Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14							0.00	
X Item/Each		1			003	59746760014										
Box/Carton/Bundle/Inner Pack						COST INFORMATION WHOLESALER USE ONLY:				Y:						
X Case		24			403	59746760012			11							
Pallet					-		_		Regular Cos Invoice Cost			¢40.50	Vendor #: Whsl. Code	. 4.		
									IIIVOICE COST	(41/10) (4)		\$16.50	Fineline Co			
									As of date:				1			
													1			
							-		Ц							
1			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza			RT, LABEL AND PHOTO OF I	PRODUCT PACK	AGING and	BARCODE.					
*Please provide any additional int	formation on page	2				See new n 3 for	r Design	nated Drop Ship Only		Signatur	e.					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD 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?	SDS Hazard Classification Organic Corrosive								
Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning?	Inorganic Steroid/Androgen	Oxidizer Contact Hazard							
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 No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	No						
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	Is the product a NIOSH hazardous drug? If yes, indicate which:	No							
c. DOT Hazard Class	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?	No	21777 Mazardodo 77 dolo 00001		Tracto Charactoriorio					
(if yes, answer a-e below and provide SDS)	140	REMS or REGISTRY RESTRICTIONS							
a. UN/Identification Number									
b. Proper Shipping Name		Is there a REMS on this product?	No						
c. DOT Hazard Class d. Packing Group		If Yes, is it managed with a pharmacy registry? Website URL:							
e. Inhalation Hazard?	No	Woodle Cite.							
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		5540							
Is this a reportable quantity? No RQ Threshold:		REMS Program Manager Name:		Phone:					
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:		1 10.10.					
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:							
No (if yes, identify method below)		Provider Name:		DEA #: NCPDP#:					
Limited Quantity Consumer Commodity, ORM-D	Site Enrollment Number assigned by Supplier:		NCPDP#: NPI #:						
Small Quantity (49 CFR 173.4)		зу саррион							
Special Permit; DOT-SP		Comments							
Special Provision (listed in Column 7 of 49 CFR 172.101);									
SP#		Registry:		Phone:					
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		FIIOTIE.					
Is the Product									
Controlled Substance? No Controlled Substance Code		R	ETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II)	No								
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged:							
CLASS OF TRADE RESTRICTION:	140	Is product returnable for credit:							
	Yes	URL/Link to returns policy:							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices									
Restricted to retail pharmacy only:	No	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)	No No	If so, which states? Other requirements? Comments?							
Comments:	140	ii 30, wiilon states: Other requirements: Other ents:							
Commonto.									
MIS	SCELLANEC	DUS NOTES and/or Image of Product Barcode:							
- Wild		The red dilator image of Floudet Barcode.							



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:				
F	Name: Phone:	Ships regular ground for 3-10 days receipt:				
Expedited Freight Charg	ges 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:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Infor	rmation Required to Process 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?				
Mis	scellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				