

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

Version 2021						Introduction Type	e: New Item	_	X Final Version			Date:	1/26	/2023
			PRODUCT INFORMAT	TION					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 produc			his product	oduct			
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				1			<u> </u>	ther Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Chlortha	alidone Tablets					1	(write in)	toquiioiiioiit				
Selling Unit NDC:	59746-761-01	umo:	Unit of Use NDC:			UPC: 3-	59746-761-01-1	- I N	otes					
UDI			CVX Code:			MVX Code:								
												1		
Description:	Chiorthalidone 50	img 100ct Tablets											No	
A ative leave dieut(a).		Chlorthalidone						- IS	this product to be shipped	to customers on	ary ice?		No	.]
Active Ingredient(s):		Chlorthalidone	h Contact for to	mperature excursion que	actions:									
URL for Additional Product Information: www.cadista.com/products/full-product-list									ame:	estions.	Customer S	envice		
Address:	207 Kiley Drive	www.cauista.com	i/products/full-produc	<u>t-list</u>	1	Address 2:			umber:		(800) 313-4			
City:	Salisbury				State:		ip: 21801	- 1	roup E-mail:		` '	service@ca	adista com	
Key Contact:	Customer Service	9			Email:	customer.service		1	oup =a		castomer	SCI VICCIO CC	adista.com	
Phone Number:	(800) 313-4623				Fax:	(215) - 443 - 9646		c. Special regula	ations for product in any	states?			No	1
Product Therapeutic Classification		Oral Hypertensive				, ,			pecial returns requirement				No	
,		71			1			_	,					1
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship (Only			11		la) fram limbt?			No	1
a legend device?		NI.	Is the Product	Neither	Jilly		100 count	e. Shelf life:	rotect product (unit of sa	ile) from light?			36	Months
if yes, enter class #		No	Orphan Drug Status	iveittiei		Size:	100 Count		nitial shelf life at launch (i	if different).			36	Months
a product kit?		No	Orphan Drug Status				50mg	"	iluai sileli ille at laulicii (i	ii dillerenty.				Wionins
if yes, list NDCs of		INU	FDA Approval Status			Strength:	Some			ORDER INFORM	MATION			
component parts			. Dririppi oral Glatac				Tablet							
reverse numbered?		No				Dosage Form:	1.000	ll u	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		Yes	Allergens Present						X Bottle		1 Bottle of 1			
latex-free?		Yes	J				Flat Round Tablet		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:			Ampule			-		
correctional institution block?		Yes				Product Color:	Light Green		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	'I' / '3'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					Froduct Imprint			Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
hospital scanning?			Is this product covered u	nder the					Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	ΓAA)?	No				Vial Power Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS										
					Au		Authorized Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB					se	ction fields are not applicable	Rec. sell unit to		-		nit to pharm	acy:	
II. Generic Equivalent to What Brand?: Hygroton®				1 Bottle of 100 tablets				X Each						
		DRUG GURRI V	OUAN SECURITY AST	DOOD AV INITO	MATION			(Write-in, e.g. 1	Vial)			Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	RMATION			_				Milliliter		
Does supplier meet DSCSA defin	ition of manufactu	ror?	Yes	_	GLN:	8904184010027			ITEM	AND PACKING I	NEORMATIO	V		
Is product exempt from DSCSA?			No	-	JLII.	5504104010021			TI LIN	THE PROMING I				
•			·		000	0250740		1		Dimens	ions (US msr	ata \	M - I	0-1
If yes, select exemption: Other exemption - Write in:					GCP:	0359746		1	Weight Lbs.	Dimens	Width	Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If you was or	riginal product		Item/Each:						rieces
Is product repackaged?	s exclusive distrib	utor?	No	-		irect from mfr?		Relificacii.	0.085	1.54	1.54	3.35	7.94	1
Has FDA granted waiver/exception			No	_	•	ce manufacturer for re	epackaged product	Box/Carton/Bun	dle/					
If yes, attach documentation fro			·		oriuo ooui		puoliugou pi ouuot	Inner Pack:	4.07				0.00	
, ,								Case:	0.00	0.45	0.5	4.00	005.07	0.4
		GTIN	AND HIBCC PRODUCT IN	NFORMATION					2.98	9.45	6.5	4.33	265.97	24
								Pallet:					0.00	
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14						0.00	
X Item/Each		1			003	59746761011								
Box/Carton/Bundle/Inner Pack							COST INFORMATION			WHOLESALER USE ONLY:				
X Case		24			403	59746761019								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (W.	AC) (\$)	\$22.00	Whsl. Code			
								11			Fineline Co	de:		
								As of date:			1			
	_													
				0		II BLOWLET	NEDT 105 110 010							
*Please provide any additional inf			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza		SERT, LABEL AND PHOTO OF I		ING and BARCODE.					



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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): a. Cytotoxic? No SDS Hazard Classification 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? No Inorganic Oxidizer 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 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 REMS: Is this a reportable quantity? 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: No Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



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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 #:	Fax Number: Fax Number: Phone No.: Site Address: Name: Phone: Phone: rges or Other Designated Drop Ship Fees:	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: Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each orde		Overnight receipt available:						
Drop Ship service fee billed with each order Drop Ship miscellaneous fees billed: Comments:	T	PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday Priority Overnight receipt available:						
Cla	ss of Trade Restriction:	PO Receipt Cut off time:						
No restriction: Select YES if sold to retail ph Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician Restricted from US territories? (explain in c Comments:	narmacy, hospitals, clinics and physician offices a offices only: comments)	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:						
Other Data Inf	ormation 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?						