

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

Version 2021						Introduction T	ype:	Post Launch Change		x	Final Version			Date:	7/12/	/2021
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUII	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application:					tion:	ANDA	a. Temperatu	ure – Indicat	e the USP temp	erature range for ti	nis product.					
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203253 Temperature Range Controlled Room - between 20 and 25 C (68° - 77° F)																
Medical Device Class, if applicat	ple:										-					
DUNS:	022490515									Other Terr	perature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Spire	onolactone Tablets							(write	e in)					
Selling Unit NDC:	59746-216-05		Unit of Use NDC:			UPC:	3-59746-2	16-05-4		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Spironolactone 2	5mg 500 Tablets								Is this pro	duct to be shippe	d to customers on id	ce?		No	
								Is this pro	duct to be shippe	d to customers on d	ry ice?		No			
Active Ingredient(s):		Spironolactone							h Contact fo	r tomporati	ire excursion qu	astions:				
URL for Additional Product Inform	ation.	www.cadista.c	om/products/full-produc	+-list					D. Contact 10	Name:	ire excursion qu	estions.	Customer S	ervice		
Address:	207 Kiley Drive			<u>, , , , , , , , , , , , , , , , , , , </u>		Address 2:				Number:			(800) 313-46			
City:	Salisbury				State:	MD	Zip: 2	1801		Group E-	mail:		customer.	service@ca	adista.com	
Key Contact:	Jackie Emershaw				Email:	Jackie.Emersha		<u>com</u>								
Phone Number:	(410) 912-3722	410) 912-3722 Fax:			(215) - 443 - 9646			c. Special regulations for product in any states?				No				
Product Therapeutic Classificatio	n:	Antihypertensive								Special re	turns requiremen	ts for this product?			No	
						PRODUCT	SCOLDER			duet (a a la) un d'art d'				N-	1
	ADDITI	ONAL PRODUCT I				PRODUCT I	JESCRIPTI	ON INFORMATION	a. Store proc		sale) upright?				No	1
The product is?			Is the Product	Direct-Ship (Only					Protect p	roduct (unit of sa	ale) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	500) count	e. Shelf life:	Initial at a	If life at launch (if different).			24	Months Months
a product kit?		No	Orphan Drug Status				25r	na		initial she	in line at launch (ir amerent):				wonths
if yes, list NDCs of		IND	FDA Approval Status			Strength:	201					ORDER INFORM	ATION			
component parts						Dosage Forr	TA	BLET								
reverse numbered?		No				Dosage For				Unit of Sa				NDC selling	unit?	
co-licensed?		No	Allergens Present							X			1 bottles of s			
latex-free?		Yes				Product Sha	pe: Ro	und, Biconvex			Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		No					Bro				Ampule Glass		Minimum o	rder quantity		Yes
opioid?		Yes No				Product Cold	or:	JWIT			Tube		Willing	idei quantity	1	Tes
Cannabinoid?		No	Country of Origin	IN		Destauto	TL	216			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for		, ,			Product Imp	rint:				Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?			Is this product covered								Vial Powder Sql		48	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No						Vial Power Multi			Inner/Cartor	n/Pack	
											Other: Write In		1	Case		
			FOR GENERIC DRUG PR	ODUCTS					_							
					Δ	uthorized Generic	*If Authori	zed Generic, other	PHARMACY ORDER / BILL UNIT							
L Orenne Beek Beting	AB					dinonized Generic		lds are not applicable	Rec. sell unit	t to oustom				uitte uberm		
I. Orange Book Rating: II. Generic Equivalent to What Bra		Aldactone								ottles of 500			X X X	nit to pharm Each	acy:	
							(Write-in, e.g. 1 Vial)			Gram						
		DRUG SUPP	PLY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION					, .,				Milliliter		
														•		
Does supplier meet DSCSA defini	tion of manufactur	rer?	Yes	_	GLN:	8902805000006					ITEN	I AND PACKING IN	IFORMATIO	N		
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:	0359746					Weight Lbs.		ons (US msn	-	Volume	Saleable #
Other exemption - Write in:			No		K	riginal preduct			Ham/Fach.			Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	exclusive distribu	itor?	No	-		riginal product irect from mfr?			Item/Each:		0.23	1.9	1.9	4	14.44	1
Has FDA granted waiver/exception			No	-	-	rce manufacturer fo	or repackad	jed product	Box/Carton/E	Bundle/					0.00	
If yes, attach documentation from									Inner Pack:						0.00	
									Case:		13.25	15.63	11.89	6.1	1133.63	48
		G	IN AND HIBCC PRODUCT I	NFORMATION					Deller							
Saleable Unit of Measure	9	aleable Quantity	HIBCC		GT	IN-14		nit of Use GTIN-14	Pallet:						0.00	
X Item/Each	3	1			_	359746216054										
Box/Carton/Bundle/Inner Pack								COST	INFORMATION			WHOLESAL	ER USE ONL	.Y:		
X Case		48			403	359746216052										
Pallet	7								Regular Cost				Vendor #:			
	-						-		Invoice Cost	: (WAC) (\$)		\$27.90	Whsl. Code			
	-						-		As of date:	1			Fineline Co	ue:		
	-								As of uale:							
			Attach copy of SAFETY DA	ATA SHEET (SC	S) or non haza	ard letter, PACKAGE	INSERT, L	ABEL AND PHOTO OF F	PRODUCT PACK	AGING and	BARCODE.					
*Please provide any additional inf	ormation on page	2						d Drop Ship Only.		Signature						

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

Version 2021 For Des	ignated Drop Ship Only Products, Please Use Page 3						
MATERIA	L HAZARD 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? N							
Is the product a CA Prop 65 reproductive toxicant? N Does the product label bear a CA Prop 65 warning? N	Inorganic Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard? N d. Does this product require special clean-up instructions? N (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? N	Does the product have an Aerosol class? If yes, identify No NFPA Storage Level: NFPA Storage Level:						
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name	If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion)						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard? N Is this product regulated for shipment by IATA? N							
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:						
e. Inhalation Hazard? N Is the product restricted for air shipment? If so, indicate restriction: N Passenger Cargo Passenger & Cargo							
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 Limited Quantity method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: Phone: 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 #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? No ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: N CLASS OF TRADE RESTRICTION:	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 Ye Restricted to retail pharmacy only:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
MISCELL	ANEOUS NOTES and/or Image of Product Barcode:						



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Version 2021 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:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
Class of Trade Restriction:	Priority Overnight receipt available: 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)	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?