



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Product Post Launch Change Final Version

Date: 10/16/19

PRODUCT INFORMATION	
Company Name:	Jubilant Cadista Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	Application: ANDA
DUNS:	022490515
Proprietary Name (If Applicable) and Established Name:	Spironolactone Tablet
Selling Unit NDC:	59746-0216-05
UDI	Individual Unit NDC: CVX Code: MVX Code: UPC: 3-59746-216-05-4
Description:	Spironolactone 25mg Tablet 500 count
Active Ingredient(s):	Spironolactone
URL for Additional Product Information:	www.cadista.com
Address:	207 Kiley Drive Salisbury Key Contact: Jackie Emershaw Phone Number: (410) 912-3722
State:	MD
Address 2:	Zip: 21801
Email:	Jackie.Emershaw@cadista.com
Fax:	(215) 443-9646
Product Therapeutic Classification:	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
reverse numbered?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
co-licensed?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is the Product... Is the Product...	Direct-Ship Only <input type="checkbox"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	500ct
Strength:	25mg
Dosage Form:	TAB
Product Shape:	Tablet
Product Color:	Brown
Product Imprint:	TL 216

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB <input type="checkbox"/> Authorized Generic <input type="checkbox"/> If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	Aldactone

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is product exempt from DSCSA?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, select exemption:	GLN: 8902805000006
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	If Yes, was original product purchased direct from mfr? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
	If yes, attach documentation from FDA.

GTIN PRODUCT INFORMATION				
Serialized?	Level	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> Item	<input type="checkbox"/> Unit	1	00359746216054
If not, when?	<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="checkbox"/> Unit		
Items aggregated?	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/> Unit	48	40359746216052
	<input type="checkbox"/> Pallet	<input type="checkbox"/> Unit		
	<input type="checkbox"/> Linear	<input type="checkbox"/> Unit		
	<input type="checkbox"/> 2D	<input type="checkbox"/> Unit		
	<input type="checkbox"/> 2D	<input type="checkbox"/> Unit		
	<input type="checkbox"/> 2D	<input type="checkbox"/> Unit		
	<input type="checkbox"/> 2D	<input type="checkbox"/> Unit		
	<input type="checkbox"/> 2D	<input type="checkbox"/> Unit		
	<input type="checkbox"/> 2D	<input type="checkbox"/> Unit		

SPECIAL HANDLING AND STORAGE REQUIREMENTS	
a. Temperature - Indicate the USP temperature range for this product.	Temperature Range: Controlled Room - between 20 and 25 C (68° - 77°)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Contact for temperature excursion questions:	Name: Customer Support Number: (800) 313-4623 Group E-mail:
c. Special regulations for product in any states?	Special returns requirements for this product? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Shelf life:	Initial shelf life at launch (if different): <input type="text"/> Months <input type="text"/> Months

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Case of 48 bottles
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Case
<input type="checkbox"/> Other: Write In	

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text"/> (Write-in, e.g. 1 Vial)	<input type="text"/> Each <input type="text"/> Gram <input type="text"/> Milliliter

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Box/ Carton/ Bundle/ Inner Pack:	0.23	1.87	4.37	1.87	15.28	1
Case:	13.25	15.63	6.1	11.89	1133.63	48
Pallet:					0	
UPC:	Case:					
	Carton:					

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$27.90	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Is the product a CA Prop 65 carcinogen? Yes

Is the product a CA Prop 65 reproductive toxicant? No

Does the product label bear a CA Prop 65 warning? No

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? No

(if yes, answer a-e below and provide SDS)

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

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

(if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:

Is it a scheduled listed chemical product?

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/>	
Is the product a NIOSH hazardous drug? Yes	
If yes, indicate which: <input style="width: 100%;" type="text"/>	
FDA Pregnancy Category C; Black Box warning for tumorigenicity in laboratory studies	

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments:

Registry:

Registry Program Contact Name: Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: (410) 912-3722

Is product returnable for credit:

URL/Link to returns policy: www.cadista.com

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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 <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="checkbox"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	Return Instructions Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>