



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Pre-Launch Change Post Launch Change Final Version

Date: 12/9/2020

PRODUCT INFORMATION

Company Name: Jubilent Cadista Pharmaceuticals Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A040659
 DUNS: 022490515
 Proprietary Name (If Applicable) and Established Name: MECLIZINE HYDROCHLORIDE TABLETS
 Selling Unit NDC: 59746-0121-06 Individual Unit NDC: _____ UPC: 3-59746-121-06-8
 UDI: _____ CVX Code: _____ MVX Code: _____
 Description: Meclizine 25mg Tablets 100ct.
 Active Ingredient(s): Meclizine
 URL for Additional Product Information: www.cadista.com
 Address: 207 Kiley Drive Address 2: _____
 City: Salisbury State: MD Zip: 21801
 Key Contact: Jackie Emershaw Email: Jackie.Emershaw@cadista.com
 Phone Number: (410) 912-3722 Fax: (215) 443-9646
 Product Therapeutic Classification: Motion Sickness

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device? Yes
 reverse numbered? No
 co-licensed? No
 Is the Product... Direct-Ship Only
 Is the Product...
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose NDC, indicate NDC here: _____
 Country of Origin: _____
 Is this product covered under the Trade Agreements Act (TAA)? Yes

PRODUCT DESCRIPTION INFORMATION

Size: 100ct
 Strength: 25mg
 Dosage Form: TAB
 Product Shape: Oval
 Product Color: Yellow
 Product Imprint: Debossed TL 121

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° F)
 Other Temperature Range Requirement (write in): _____
 Is this product to be shipped to customers on ice? No
 Is this product to be shipped to customers on dry ice? 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? No
 d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light? No
 e. Shelf life:
 Initial shelf life at launch (if different): 24 Months
 24 Months

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Antivert®

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No
 Is product exempt from DSCSA? Yes No
 If yes, select exemption: _____
 Other exemption - Write in: _____
 Is product repackaged? Yes No
 Is product sold by manufacturer's exclusive distributor? Yes No
 Has FDA granted waiver/exception/exemption for product? Yes No
 GLN: 0359746000004
 If Yes, was original product purchased direct from mfr? Yes No
 If yes, attach documentation from FDA.

GTIN PRODUCT INFORMATION

	Serialized?	If not, when?	Items aggregated?	Level		Saleable Unit		Quantity	GTIN-14
				Item	Box/Case/Pallet	Unit	Unit		
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1	00359746121068
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	48	40359746121066
<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

ORDER INFORMATION

Unit of Sale: Bottle Box/Case Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Power Multi Other: Write In _____
 What is the NDC selling unit?
 1 Case of 48 Bottles
 (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity? Yes
 If Yes, how many of which package type?
 48 Each
 Inner/Case/Pack
 Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? _____
 (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.13	1.9	4	1.9	14.44	1
Box/Case/Bundle/Inner Pack:					0	
Case:	6.85	11.25	5	11.5	876.88	48
Pallet:					0	
UPC:	Case:					
	Carton:					

COST INFORMATION

Regular Cost _____ Vendor #: _____
 Invoice Cost (WAC) (\$) \$19.09 Whsl. Code #: _____
 Federal Excise Tax Per Unit of Sale _____
 As of date: _____
 Wholesaler Use Only:
 Fine Line Code: _____

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? | |
| Is the product a CA Prop 65 carcinogen? | No |
| 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?
(If yes, attach SDS with special instructions.) | No |
| e. Does the product contain DEHP? | No |
| Is this product regulated for shipment by DOT or IATA?
(if yes, answer a-e below and provide SDS) | No |

- | | |
|-----------------------------|--|
| 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"/> Inorganic
<input type="checkbox"/> Steroid/Androgen

<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100px;" type="text"/> | <input type="checkbox"/> Corrosive
<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Contact Hazard

Is the product a NIOSH hazardous drug? No
If yes, indicate which: <input style="width: 100px;" type="text"/> |
|--|--|

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:
 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 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 <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> Yes Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Yes 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" value="48"/> Supplier's Customer Service Number: <input type="text" value="(410) 912-3722"/> 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="text"/> 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"/> ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>
Other Data Information Required to Process PO:	
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:	
<input type="text"/>	