



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  New Product  Post Launch Change Final Version

Date: 10/15/19

**PRODUCT INFORMATION**

Company Name: Jubilant 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 Tablet  
 Selling Unit NDC: 59746-0121-10 Individual Unit NDC: \_\_\_\_\_ UPC: 3-59746-121-10-5  
 UDI \_\_\_\_\_ CVX Code: \_\_\_\_\_ MVX Code: \_\_\_\_\_  
 Description: Meclizine 25mg Tablets 1000ct.  
 Active Ingredient(s): Meclizine  
 URL for Additional Product Information: www.cadista.com  
 Address: 207 Kiley Drive Salisbury, MD 21801  
 Key Contact: Jackie Emershaw Email: Jackie.Emershaw@cadista.com  
 Phone Number: (410) 912-3722 Fax: (215) 443-9646  
 Product Therapeutic Classification: \_\_\_\_\_

**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?  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?  No  
 Special returns requirements for this product?  No  
 d. Store product (unit of sale) upright?  No  
 Protect product (unit of sale) from light?  No  
 e. Shelf life:  24 Months  
 Initial shelf life at launch (if different):  24 Months

**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)?

**PRODUCT DESCRIPTION INFORMATION**

Size: 1000ct  
 Strength: 25mg  
 Dosage Form: TAB  
 Product Shape: Oval  
 Product Color: Yellow  
 Product Imprint: Debossed TL 121

**ORDER INFORMATION**

Unit of Sale:  Bottle,  Box/Carton,  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 12 Bottles (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity?  Yes  
 If Yes, how many of which package type?  
 12 Each,  Inner/ Carton/Pack,  Case

**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®

**PHARMACY ORDER / BILL UNIT**

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

**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.

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.63	2.63	5.5	2.63	38.04	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	8.05	11	6.25	8.5	584.38	12
Pallet:					0	
UPC:	Case:					
	Carton:					

**GTIN PRODUCT INFORMATION**

Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Item	Saleable Unit		
<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	1	00359746121105
			<input checked="" type="checkbox"/>	Case	12	40359746121103
			<input type="checkbox"/>	Pallet		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	2D		

**COST INFORMATION**

Regular Cost: \_\_\_\_\_  
 Invoice Cost (WAC) (\$): \$190.89  
 Federal Excise Tax Per Unit of Sale: \_\_\_\_\_  
 As of date: \_\_\_\_\_  
 Vendor #: \_\_\_\_\_  
 Whsl. Code #: \_\_\_\_\_  
 Fineline 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? No

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? 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#

### SDS Hazard Classification

Organic  Corrosive

Inorganic  Oxidizer

Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

### 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

### 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?

### 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?

### 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:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

