



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Jubilant Cadista Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	091116
Application:	ANDA
DUNS:	022490515
Proprietary Name (if Applicable) and Established Name:	Children's Cetirizine Hydrochloride Chewable Tablets (Allergy)
Selling Unit NDC:	59746-0285-32
Individual Unit NDC:	
UDI	
CVX Code:	
UPC:	3-59746-285-32-6
MXV Code:	
Description:	Children's Cetirizine Hydrochloride Chewable Tablets (Allergy) 5mg 30ct
Active Ingredient(s):	Cetirizine
URL for Additional Product Information:	
Address:	207 Kiley Drive
City:	Salisbury
Key Contact:	Jackie Emershaw
Phone Number:	(410) 912-3722
Product Therapeutic Classification:	
State:	MD
Address 2:	
Zip:	21801
Email:	Jackie.Emershaw@cadista.com
Fax:	(215) 443-9646

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 Service
Number:	(800) 313-4623
Group E-mail:	
c. Special regulations for product in any states?	
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
Is the Product... a legend device? <input type="checkbox"/> Yes reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No	Size: 30ct
Is the Product... Is the Product... Is the Product...	Strength: 5mg
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>	Dosage Form: Tablet
If Unit Dose NDC, indicate NDC here: <input type="text"/>	Product Shape: Circular, flat faced
Country of Origin: <input type="text"/>	Product Color: orange
Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/>	Product Imprint: C285

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 case of 54 cartons
<input checked="" type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Sgl	54 Each
<input type="checkbox"/> Vial Liquid Multi	Inner/ Carton/ Pack
<input type="checkbox"/> Vial Powder Sgl	Case
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating: <input type="text" value="N/A"/>	<input type="checkbox"/> Authorized Generic
II. Generic Equivalent to What Brand?: <input type="text" value="Zyrtec Chewable"/>	*If Authorized Generic, other section fields are not applicable

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

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.07	5.12	1.18	3.5	21.15	0
Case:	3.75	11.42	10.83	11.22	1387.67	54
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION					
Serialized?	Level	Saleable Unit		Quantity	GTIN-14
		Item	Unit		
<input checked="" type="checkbox"/> Yes	Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/>	1	00359746285326
If not, when?	Case	<input type="checkbox"/> 2D	<input checked="" type="checkbox"/>	54	40359746285324
Items aggregated?	Pallet	<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		
		<input type="checkbox"/> 2D	<input type="checkbox"/>		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$94.99	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	7/27/2017		

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? 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?

RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?
(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

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:

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:

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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/> Units</p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="checkbox"/></p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/></p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="checkbox"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 50px;" type="text"/></p>
Other Data Information Required to Process PO:	Miscellaneous Notes:
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p><input style="width: 100%; height: 100px;" type="text"/></p>
ADDITIONAL INFORMATION	
<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>	