



# 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
DUNS:	022490515
Proprietary Name (if Applicable) and Established Name:	Children's Cetirizine Hydrochloride Chewable Tablets (Allergy)
Selling Unit NDC:	59746-0286-32
Individual Unit NDC:	
UPC:	3-59746-286-32-3
CVX Code:	
MXV Code:	
Description:	Children's Cetirizine Hydrochloride Chewable Tablets (Allergy) 10mg 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:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
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>b. Contact for temperature excursion questions:</b>	
Name:	Customer Service
Number:	(800) 313-4623
Group E-mail:	
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
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... Is the Product...	
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:	30ct
Strength:	10mg
Dosage Form:	Tablet
Product Shape:	Circular, flat faced
Product Color:	orange
Product Imprint:	C286

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	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	54 Each
	Inner/ Carton/ Pack
	Case

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
	Each
	Gram
	Milliliter

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.09	5.12	1.18	3.5	21.1456	
Case:	4.32	11.42	10.83	11.22	1387.67389	54
Pallet:					0	
UPC:						
	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit		Quantity	GTIN-14	Item
		Item	Unit			
Yes		<input checked="" type="checkbox"/>		1	00359746286323	Box/ Carton/ Bundle/ Inner Pack
If not, when?		<input checked="" type="checkbox"/>		54	40359746286321	Case
Items aggregated?			<input checked="" type="checkbox"/>			Pallet

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)?

ARCOS Reportable?

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?

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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/> Yes</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td>Fax Number:</td> <td colspan="3"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td>Fax Number:</td> <td colspan="3"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Phone No.:</td> <td colspan="3"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Site Address:</td> <td colspan="3"><input style="width: 100%;" type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 50px;" type="text" value="54"/> Units</p> <p>Supplier's Customer Service Number: <input style="width: 100%;" type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/></p>	a. EDI	<input type="checkbox"/> Yes					b. Autofax	<input type="checkbox"/> Yes	Fax Number:	<input style="width: 100%;" type="text"/>			c. Fax	<input type="checkbox"/> Yes	Fax Number:	<input style="width: 100%;" type="text"/>			d. Phone only	<input type="checkbox"/>	Phone No.:	<input style="width: 100%;" type="text"/>			e. Supplier Web Site only	<input type="checkbox"/>	Site Address:	<input style="width: 100%;" type="text"/>			<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 150px;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/></p>
a. EDI	<input type="checkbox"/> Yes																														
b. Autofax	<input type="checkbox"/> Yes	Fax Number:	<input style="width: 100%;" type="text"/>																												
c. Fax	<input type="checkbox"/> Yes	Fax Number:	<input style="width: 100%;" type="text"/>																												
d. Phone only	<input type="checkbox"/>	Phone No.:	<input style="width: 100%;" type="text"/>																												
e. Supplier Web Site only	<input type="checkbox"/>	Site Address:	<input style="width: 100%;" type="text"/>																												
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																														
<p>Expedited freight fees billed with each order: <input style="width: 50px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%;"> <tr><td><input type="checkbox"/> Monday</td></tr> <tr><td><input type="checkbox"/> Tuesday</td></tr> <tr><td><input type="checkbox"/> Wednesday</td></tr> <tr><td><input type="checkbox"/> Thursday</td></tr> <tr><td><input type="checkbox"/> Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method: Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 50px;" type="text"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 50px;" type="text"/> EDI: <input style="width: 50px;" type="text"/></p> <p>Overnight Fees apply: <input style="width: 50px;" type="text"/></p> <p>Other fees apply: <input style="width: 50px;" type="text"/></p>	<input type="checkbox"/> Monday	<input type="checkbox"/> Tuesday	<input type="checkbox"/> Wednesday	<input type="checkbox"/> Thursday	<input type="checkbox"/> Friday																									
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<input type="checkbox"/> Thursday																															
<input type="checkbox"/> Friday																															
Class of Trade Restriction:	Return Instructions																														
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50px;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 50px;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 100%;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 50px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/></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:	ADDITIONAL INFORMATION																														
<p>Patient Procedure Date: <input style="width: 100%;" type="text"/></p> <p>Physician Name: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 100%;" type="text"/></p> <p>Physician State License #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 100%;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text"/></p>																														
Miscellaneous Notes:																															
<p><input style="width: 100%; height: 100px;" type="text"/></p>																															