



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:	

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	
Is the Product... a legend device?	Yes
reverse numbered?	No
co-licensed?	No
Is the Product... 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: 5mg

Dosage Form: Tablet

Product Shape: Circular, flat faced

Product Color: orange

Product Imprint: C285

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicableII. Generic Equivalent to What Brand?:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? GLN: Is product exempt from DSCSA? Other exemption: (Write in) Is product repackaged? If Yes, was original product purchased direct from mfr? Is product sold by manufacturer's exclusive distributor? If yes, attach documentation from FDA.Has FDA granted waiver/exception/exemption for product?

GTIN PRODUCT INFORMATION

Serialized?	Level	Saleable Unit		Quantity	GTIN-14
		Item	Unit		
<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	2D	1	00359746285326
<input type="checkbox"/>	Box/Case/Bundle/Inner Pack	<input type="checkbox"/>	2D		
<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	2D	54	40359746285324
<input type="checkbox"/>	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		

ORDER INFORMATION

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

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Case/Bundle/Inner Pack:	0.07	5.12	1.18	3.5	21.1456	0
Case:	3.75	11.42	10.83	11.22	1387.67389	54
Pallet:						0
UPC:						

COST INFORMATION

Regular Cost Invoice Cost (WAC) (\$) 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?

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

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen 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" style="border: 1px solid black; height: 15px;"></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/> Yes</td> <td>Fax Number:</td> <td colspan="3" style="border: 1px solid black; height: 15px;"></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Phone No.:</td> <td colspan="3" style="border: 1px solid black; height: 15px;"></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" style="border: 1px solid black; height: 15px;"></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: 80%;" type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input style="width: 80%;" type="text"/> Phone: <input style="width: 80%;" type="text"/></p>	a. EDI	<input type="checkbox"/> Yes					b. Autofax	<input type="checkbox"/> Yes	Fax Number:				c. Fax	<input type="checkbox"/> Yes	Fax Number:				d. Phone only	<input type="checkbox"/>	Phone No.:				e. Supplier Web Site only	<input type="checkbox"/>	Site Address:				<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 100px;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 40px;" type="text"/> Hours <input style="width: 40px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 40px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 40px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 40px;" type="text"/></p>
a. EDI	<input type="checkbox"/> Yes																														
b. Autofax	<input type="checkbox"/> Yes	Fax Number:																													
c. Fax	<input type="checkbox"/> Yes	Fax Number:																													
d. Phone only	<input type="checkbox"/>	Phone No.:																													
e. Supplier Web Site only	<input type="checkbox"/>	Site Address:																													
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: 40px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 40px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 40px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 60px;" type="text"/></p>	<p>Overnight receipt available: <input style="width: 40px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 100px;" 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>Priority Overnight receipt available: <input style="width: 40px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 100px;" type="text"/></p> <p>Saturday Overnight receipt available: <input style="width: 40px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 100px;" type="text"/></p> <p>Order receipt method: Phone: <input style="width: 40px;" type="text"/> Phone #: <input style="width: 40px;" type="text"/> Fax: <input style="width: 40px;" type="text"/> Fax #: <input style="width: 40px;" type="text"/> EDI: <input style="width: 40px;" type="text"/></p> <p>Overnight Fees apply: <input style="width: 40px;" type="text"/></p> <p>Other fees apply: <input style="width: 40px;" type="text"/></p>	<input type="checkbox"/> Monday	<input type="checkbox"/> Tuesday	<input type="checkbox"/> Wednesday	<input type="checkbox"/> Thursday	<input type="checkbox"/> Friday																									
<input type="checkbox"/> Monday																															
<input type="checkbox"/> Tuesday																															
<input type="checkbox"/> Wednesday																															
<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: 40px;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 40px;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 40px;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 40px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 100px;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 40px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 100px;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 40px;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 30px;" type="text"/></p>																														
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																														
<p>Patient Procedure Date: <input style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 100px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 100px;" type="text"/></p> <p>Physician State License #: <input style="width: 100px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 100px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 100px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 40px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 40px;" type="text"/></p>																														
Miscellaneous Notes:																															
<input style="width: 100%; height: 60px;" type="text"/>																															