



# 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):	201506
DUNS:	022490515
Proprietary Name (If Applicable) and Established Name:	Valacyclovir Tablet
Selling Unit NDC:	59746-0325-30
Individual Unit NDC:	
UPC:	3-59746-325-30-5
UDI	
CVX Code:	
MXV Code:	
Description:	Valacyclovir Tablet 1000mg 30ct
Active Ingredient(s):	Valacyclovir
URL for Additional Product Information:	www.cadista.com
Address:	207 Kiley Drive Salisbury Key Contact: Jackie Emershaw Phone Number: (410) 912-3722
State:	MD
Zip:	21801
Email:	Jackie.Emershaw@cadista.com
Fax:	(215) 443-9646
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°)
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 Support
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... Direct-Ship Only	
Is the Product... Direct-Ship Only	
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:	1000mg
Dosage Form:	TAB
Product Shape:	capsule shaped
Product Color:	Blue
Product Imprint:	"C325" "1000"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Case of 48 bottles
<input 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?
	48 Each
	Inner/Cartron/Pack
	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Valtrex
<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:
(Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
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/Cartron/Bundle/Inner Pack:	0.18	1.87	4.37	1.87	15.28	1
Case:	9.8	15.25	5.5	11.75	985.53	48
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Saleable Unit	Unit		
<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	Item	1	00359746325305
			<input checked="" type="checkbox"/>	Box/Cartron/Bundle/Inner Pack		
			<input checked="" type="checkbox"/>	Case	48	40359746325303
			<input checked="" type="checkbox"/>	Pallet		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	Linear		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	Linear		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	Linear		
			<input type="checkbox"/>	2D		
			<input type="checkbox"/>	Linear		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$34.93	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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#

### 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

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:

### 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 style="width: 100px;" type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input style="width: 100px;" type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input style="width: 100px;" type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input style="width: 150px;" type="text"/></p> <p>Minimum Order Quantity: <input style="width: 150px;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 250px;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p style="margin-left: 20px;">Name: <input style="width: 150px;" type="text"/></p> <p style="margin-left: 20px;">Phone: <input style="width: 150px;" type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 100px;" type="text"/> <input style="width: 100px;" 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 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 style="width: 100px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 100px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 100px;" type="text"/></p> <p>Comments: <input style="width: 350px; height: 50px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 100px;" type="text"/> <input style="width: 100px;" 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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 100px;" type="text"/> <input style="width: 100px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 100px;" type="text"/> <input style="width: 100px;" type="text"/></p> <p>Order receipt method:</p> <p>Phone: <input style="width: 100px;" type="text"/> Phone #: <input style="width: 100px;" type="text"/></p> <p>Fax: <input style="width: 100px;" type="text"/> Fax #: <input style="width: 100px;" type="text"/></p> <p>EDI: <input style="width: 100px;" type="text"/></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: 350px; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 100px;" type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input style="width: 150px;" 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: 350px; height: 40px;" 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: 250px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 250px;" type="text"/></p> <p>Physician State License #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 250px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<input style="width: 100%; height: 100%;" type="text"/>	