



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 Introduction Type: Post Launch Change Final Version Date: 7/12/2021

PRODUCT INFORMATION		
Company Name:	<input type="text"/> Jubilant Cadista Pharmaceuticals Inc.	Application:
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	<input type="text"/> 201506	AND A
Medical Device Class, if applicable:	<input type="text"/>	
DUNS:	<input type="text"/> 022490515	
Proprietary Name (If Applicable) and Established Name:	<input type="text"/> Valacyclovir HCl Capsules	
Selling Unit NDC:	<input type="text"/> 59746-325-30	Unit of Use NDC:
UDI	<input type="text"/>	CVX Code:
		MVX Code:
		UPC:
		<input type="text"/> 3-59746-325-30-5
Description:	<input type="text"/> Valacyclovir Hydrochloride 1000mg 30ct Capsules	
Active Ingredient(s):	<input type="text"/> Valacyclovir HCl	
URL for Additional Product Information:	<input type="text"/> www.cadista.com/products/full-product-list	
Address:	<input type="text"/> 207 Kiley Drive	Address 2:
City:	<input type="text"/> Salisbury	State:
Key Contact:	<input type="text"/> Jackie Emershaw	MD
Phone Number:	<input type="text"/> (410) 912-3722	Zip:
		<input type="text"/> 21801
Product Therapeutic Classification:	<input type="text"/> Antiviral	Email:
		<input type="text"/> Jackie.Emershaw@jubl.com
		Fax:
		<input type="text"/> (215) - 443 - 9646

SPECIAL HANDLING AND STORAGE REQUIREMENTS*		
a. Temperature – Indicate the USP temperature range for this product.		
Temperature Range	<input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F)	
Other Temperature Range Requirement (write in)	<input type="text"/>	
Notes	<input type="text"/>	
Is this product to be shipped to customers on ice?	<input type="text"/> No	
Is this product to be shipped to customers on dry ice?	<input type="text"/> No	
b. Contact for temperature excursion questions:		
Name:	<input type="text"/> Customer Service	
Number:	<input type="text"/> (800) 313-4623	
Group E-mail:	<input type="text"/> customer.service@cadista.com	
c. Special regulations for product in any states?		
Special returns requirements for this product?	<input type="text"/> No	
d. Store product (unit of sale) upright?	<input type="text"/> No	
e. Shelf life:		
Protect product (unit of sale) from light?	<input type="text"/> No	
Initial shelf life at launch (if different):	<input type="text"/> 24	Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?	<input type="text"/> No	Is the Product...	<input type="text"/> Direct-Ship Only
a legend device?		Is the Product...	<input type="text"/> Neither
if yes, enter class #	<input type="text"/>	Orphan Drug Status	<input type="text"/>
if yes, list NDCs of component parts	<input type="text"/>	FDA Approval Status	<input type="text"/>
reverse numbered?	<input type="text"/> No	Allergens Present	<input type="text"/>
co-licensed?	<input type="text"/> No	Country of Origin	<input type="text"/> IN
latex-free?	<input type="text"/> Yes	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text"/> No
preservative-free?	<input type="text"/> No		
correctional institution block?	<input type="text"/> Yes	Size:	<input type="text"/> 30 count
opioid?	<input type="text"/> No	Strength:	<input type="text"/> 1000mg
Cannabinoid?	<input type="text"/> No	Dosage Form:	<input type="text"/> CAPSULE
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Product Shape:	<input type="text"/> Capsule
If Unit Dose, indicate NDC here:	<input type="text"/>	Product Color:	<input type="text"/> Blue
		Product Imprint:	<input type="text"/> C325 1000

ORDER INFORMATION		
Unit of Sale		
<input checked="" type="checkbox"/> X	<input type="checkbox"/> Bottle	What is the NDC selling unit?
<input type="checkbox"/>	<input type="checkbox"/> Box/Carton	<input type="text"/> 1 bottles of 30 capsule
<input type="checkbox"/>	<input type="checkbox"/> Ampule	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/>	<input type="checkbox"/> Glass	Minimum order quantity?
<input type="checkbox"/>	<input type="checkbox"/> Tube	<input type="text"/> Yes
<input type="checkbox"/>	<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/>	<input type="checkbox"/> Vial Liquid Multi	<input type="text"/> 48 Each
<input type="checkbox"/>	<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/Carton/Pack
<input type="checkbox"/>	<input type="checkbox"/> Vial Power Multi	<input type="text"/> Case
<input type="checkbox"/>	<input type="text"/> Other: Write In	

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text"/> 1 bottles of 30 capsule	<input type="text"/> Each
(Write-in, e.g. 1 Vial)	<input type="text"/> Gram
	<input type="text"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION		
Does supplier meet DSCSA definition of manufacturer?	<input type="text"/> Yes	GLN:
Is product exempt from DSCSA?	<input type="text"/> No	<input type="text"/> 8902805000006
If yes, select exemption:	<input type="text"/>	
Other exemption - Write in:	<input type="text"/>	
Is product repackaged?	<input type="text"/> No	GCP:
Is product sold by manufacturer's exclusive distributor?	<input type="text"/> No	<input type="text"/> 0359746
Has FDA granted waiver/exception/exemption for product?	<input type="text"/> No	If yes, was original product purchased direct from mfr?
If yes, attach documentation from FDA.	<input type="text"/>	
	Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.18	1.87	1.87	4.37	15.28	1
Box/Carton/Bundle/Inner Pack:					0.00	
Case:	9.8	15.25	11.75	9.8	1756.04	48
Pallet:					0.00	

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> X Item/Each	<input type="text"/> 1	<input type="text"/>	<input type="text"/> 00359746325305	<input type="text"/>
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> X Case	<input type="text"/> 48	<input type="text"/>	<input type="text"/> 40359746325303	<input type="text"/>
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text"/> \$34.93	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.



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Version 2021

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? (If yes, attach SDS with special instructions.) No
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) No

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction: No

- 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 Yes Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product? No Yes

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify No

NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required No

Limited Distribution Requirement No

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned by Supplier:

NCPDP#:

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:



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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"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <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="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input 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"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<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 type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<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>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 type="text"/></p>
Miscellaneous Notes:	
<p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>