

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

						Introduction Type	pe: Post Launch Change		x Final Version			Date:	7/12/	/2021
			PRODUCT INFORMAT	ΓΙΟΝ					SPECIAL HAND	LING AND STOR	AGE REQUI	EMENTS*		
Company Name:	Jubilant Cadista Pl	harmaceuticals Inc.				Applicatio	n: ANDA	a. Temperature	e - Indicate the USP temper	ature range for the	his product.			
Application Number for NDA/AN			e).	20	1506	7.000.00	/			Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical			~,·						Tomporataro Hango					
DUNS:	022490515				1				Other Temperature Range R	equirement				
Proprietary Name (If Applicable) a		me· Valacy	clovir HCl Capsules		1				(write in)	equirement				
Selling Unit NDC:	59746-325-37	inc. valuey	Unit of Use NDC:			UPC: 3	I-59746-325-37-4		Notes					
UDI	001 10 020 01		CVX Code:			MVX Code:			110.00					
-											_			1
Description:	valacyclovir Hydro	chloride 1000mg 250	ict Capsules						Is this product to be shipped				No	
A ative la anadiant/a).		Valacyclovir HCI						_	Is this product to be shipped	to customers on a	iry ice?		No	.]
Active Ingredient(s):		valacyclovii nci						h Contact for	temperature excursion que	etione:				
URL for Additional Product Inforn	mation:	www.cadista.cor	n/products/full-product	+ liet					Name:	stions.	Customer Se	nvice		
Address:	207 Kiley Drive	www.cauista.coi	ii/pi ouucts/Tuii-pi ouuci	<u>t-list</u>	1	Address 2:			Number:		(800) 313-46			
City:	Salisbury				State:		<b>Zip:</b> 21801		Group E-mail:				dista com	
Key Contact:	Jackie Emershaw				Email:	Jackie.Emershav			Group E-mail: <u>customer.service@cadista.com</u>					
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646	· C   C   C   C   C   C   C   C   C   C	c. Special regu	ulations for product in any s	states?			No	1
Product Therapeutic Classification		Antiviral				( , , , , , , , , , , , , , , , , , , ,			Special returns requirements				No	
. round morapound diacomound	····				_				oposiai rotarrio roquirorriorito	Tor time product.				1
	ADDITIO	NAL PRODUCT INF	ORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	1
The product is 0				Direct-Ship (	Only			<b>-1</b>		a) frame lit- co				1
The product is? a legend device?			Is the Product	Neither	Only		250 count	e. Shelf life:	Protect product (unit of sal	e) from light?			No 0.4	
if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	250 count		Initial shelf life at launch (if				24	Months Months
a product kit?		NI.	Orphan Drug Status				1000mg		initial shell life at launch (if	amerent):				Wonths
if yes, list NDCs of		No	FDA Approval Status			Strength:	rooonig			ORDER INFORM	IATION			
component parts			I DA Approvai Status				CAPSULE			ORDER IN ORIN	ATION			
reverse numbered?		No				Dosage Form:	0/11 00EE		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					'll r	X Bottle		1 bottles of 2			
latex-free?		Yes	Allergens i resent				Capsule		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape	):     · · · · ·		Ampule		,	,	,	
correctional institution block?		Yes					Blue		Glass		Minimum or	der quantity	/?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	IN		Product Imprir	C325 1000		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u				-		Product Imprii	ic.		Vial Liquid Multi		If Yes, how	many of whi	ich package t	type?
hospital scanning?			Is this product covered u	nder the					Vial Powder Sql		12	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	ГАА)?	No				Vial Power Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS										
			FOR GENERIC DRUG PRO	DDUCTS										
			FOR GENERIC DRUG PRO	ODUCTS	Au		If Authorized Generic, other			RMACY ORDER				
I. Orange Book Rating:	AB		FOR GENERIC DRUG PRO	DDUCTS	Au		If Authorized Generic, other section fields are not applicable	Rec. sell unit to	o customer?	RMACY ORDER	Rx billing u		асу:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Valtrex	FOR GENERIC DRUG PRO	DDUCTS	Au			1 bott	to customer?	RMACY ORDER		Each	асу:	
		Valtrex							to customer?	RMACY ORDER	Rx billing u	Each Gram	acy:	
		Valtrex	FOR GENERIC DRUG PRO					1 bott	to customer?	RMACY ORDER	Rx billing u	Each	асу:	
II. Generic Equivalent to What Bra	and?:	Valtrex DRUG SUPPL	/ CHAIN SECURITY ACT (I		RMATION			1 bott	co customer? cles of 250 capsule 1 Vial)		Rx billing u	Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra	and?:	Valtrex DRUG SUPPL						1 bott	co customer? cles of 250 capsule 1 Vial)	IRMACY ORDER	Rx billing u	Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?:	Valtrex DRUG SUPPL	/ CHAIN SECURITY ACT (I		RMATION GLN:	8902805000006		1 bott	to customer? teles of 250 capsule 1 Viai)	AND PACKING IN	Rx billing u	Each Gram Milliliter		Salashia (
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II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  X   tern/Each   Box/Carton/Bundle/Inner Pack	and?:  ition of manufacture  s exclusive distribut  onlexemption for pre-	Valtrex  DRUG SUPPL* er?  ctor? pduct?  GTIN aleable Quantity	Y CHAIN SECURITY ACT (I Yes No No No No No No	DSCSA) INFOR	GLN: GCP: If yes, was oi purchased di Provide sour	8902805000006  0359746  riginal product irect from mfr? ce manufacturer for	ection fields are not applicable	1 bott (Write-in, e.g. 1	vo customer? eles of 250 capsule 1 Vial)  ITEM  Weight Lbs.  1	AND PACKING IN  Dimensic  Depth  3.39	Rx billing u x  IFORMATION Ons (US msn Width 3.39	Each Gram Milliliter tts.) Height 7.3	Volume (Cube) 83.89 0.00	Pieces  1  12
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Version 2021

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

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 SDS Hazard Classification b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No c. Contact Hazard? No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number Is there a REMS on this product? b. Proper Shipping Name c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Med Guide Required No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Site Enrollment Number assigned NCPDP# Limited Quantity Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



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

### Version 2021

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