

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

Version 2021						Introduction 7	Гуре:	Post Launch Change		x Fina	al Version			Date:	7/12/	2021	
PRODUCT INFORMATION								SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA									a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug) PMA/510(k)(med device):  04362  4. Temperature Range   Controlled Room – between 20 and 25 C (68° – 77° F)																	
Medical Device Class, if applicable:																	
DUNS:	022490515									Other Tempe	rature Range R	equirement					
Proprietary Name (If Applicable) a		ame: Prednis	sone Tablets							(write in	_						
Selling Unit NDC:	59746-173-10		Unit of Use NDC:			UPC:	3-5974	46-173-10-4		Notes	•						
UDI			CVX Code:			MVX Code:											
Description: Prednisone 10mg 1000ct Tablets										Is this produc	t to be shipped	to customers on i	ce?		No		
·												to customers on c			No		
Active Ingredient(s): Prednisone																	
										b. Contact for temperature excursion questions:							
URL for Additional Product Inforn														Customer Service			
Address:	207 Kiley Drive					Address 2:  MD			Number:				(800) 313-4623				
City:	Salisbury				State:	MD			Group E-mail:				customer.service@cadista.com				
Key Contact:	Jackie Emershaw (410) 912-3722				Email: Fax:	Jackie.Emersh		<u>IDI.COM</u>	c. Special regulations for product in any states?						Nie		
Phone Number:		Continuosia			l ax.	(215) - 443 - 9646			c. Special regulations for product in any states?				No No				
Product Therapeutic Classificatio	Product Therapeutic Classification: Corticosteroid Special returns requirements for this product? No																
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									d. Store produ	ict (unit of ea	le) unright?				No		
The area dept to C	ABDIII	OTTALE I RODOGI INI		Direct-Ship C	Only	TROBUCTI	3-00KI	. HON IN ORMATION	a. Store prout	-		1-3 france P 1 1 6					
The product is? a legend device?			Is the Product	Neither	Thiy			1000 count	e. Shelf life:	Protect prod	luct (unit of sal	le) from light?			No 24	Months	
if yes, enter class #		No	Is the Product Neither Orphan Drug Status			Size:		1000 count		Initial chalf li	ife at launch (i	f different):	24			Months	
a product kit?		No	Orphan Drug Status					10mg		ilitiai sileli i	ile at laulich (i	i unierenty.				WOILLIS	
if yes, list NDCs of		FDA Approval Status				Strength:		1.59				ORDER INFORM	MATION				
component parts						Danama Fam		TABLETS									
reverse numbered?		No				Dosage Form	m:			Unit of Sale			What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							X Bot	tle		1 bottle of 1	000 tablets			
latex-free?		Yes				Product Sha	npe:	Round			/Carton		(Write-in, e	g. 1 Box of 1	) Vials)		
preservative-free?		No								Am					_		
correctional institution block?		Yes				Product Col	or:	White		Gla			Minimum o	rder quantity	?	Yes	
opioid? Cannabinoid?		No	Country of Origin	US				TL 173		Tub	e I Liquid Sgl						
	init does for	No	Country of Origin	03		Product Imp	rint:	IL 1/3			l Liquid Sgi I Liquid Multi		If Yes how	many of whi	ch nackane	tvne?	
hospital scanning?	se, is item bar coded to unit dose for canning?  Is this product covered under the							Vial Liquid Multi If Yes, how many of wh Vial Powder Sql 12 Each					on package	урс.			
If Unit Dose, indicate NDC here:				Yes				Vial Power Multi					Inner/Carton	/Pack			
			_								er: Write In			Case			
			FOR GENERIC DRUG PRO	DDUCTS		-											
	Authorized Generic *If Authorized Generic, other								PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating: AB			section fields are not applicable			Rec. sell unit to customer?				Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Deltasone							1 bottle of 1000 tablets				X Each						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									(Write-in, e.g. 1 Vial)					Gram			
		DRUG SUPPLY	Y CHAIN SECURITY ACT (I	JSCSA) INFOR	RMATION				_					Milliliter			
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes	7	GLN:	0359746000004					ITEM	AND PACKING IN	NEORMATIO	J			
Is product exempt from DSCSA?	oaiiaiaota		No	-	J=	3000. 10000004											
					CCD.	0359746						Dimonei	ons (US msn	nte \	Valuma	Calaabla #	
If yes, select exemption: Other exemption - Write in:					GCP:	0309740				V	Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?			No		If yes was o	riginal product			Item/Each:								
Is product reputkaged:	exclusive distribi	utor?	No	-		irect from mfr?					0.53	1.9	1.9	4	14.44	1	
Has FDA granted waiver/exceptio			No		Provide sour	rce manufacturer fo	or repac	kaged product	Box/Carton/Bu	undle/					0.00		
If yes, attach documentation from	m FDA.			_					Inner Pack:						0.00		
									Case:		6.4	12.37	9.5	5.5	646.33	12	
		GTIN	I AND HIBCC PRODUCT IN	IFORMATION							0.1	.2.07	0.0	0.0	0.10.00		
	_								Pallet:						0.00		
Saleable Unit of Measure	٤	Saleable Quantity	HIBCC			IN-14		Unit of Use GTIN-14									
X Item/Each	1 00359			359746173104			COST INFORMATION				WHOLESALER USE ONLY:						
Box/Carton/Bundle/Inner Pack  X Case		12 4035			359746173102	746173102			COST INFORMATION				WHOLESALER USE UNLT:				
Pallet		12				33740173102	-		Regular Cost				Vendor #:				
									Invoice Cost (	WAC) (\$)		\$164.47	Whsl. Code	#:			
										-,,		7.2	Fineline Co				
									As of date:								
<u> </u>																	
*Please provide any additional inf	formation on ne		Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza			T, LABEL AND PHOTO OF F		AGING and BA	RCODE.						



Version 2021

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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:	Overnight receipt available:							
Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:	PO Receipt cut off time:  Days of week overnight is available:  Monday  Tuesday  Wednesday  Thursday  Friday  Priority Overnight receipt available:							
Class of Trade Restriction:	PO Receipt Cut off time:							
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:	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:							
Other Data Information Required to Process PO:	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?							