

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

Version 2021						Introduction Typ	e: New Item		x Final Version			Date:	8/8/	/2023
			PRODUCT INFORMA	TION					SPECIAL H	ANDLING AND STO	RAGE REQUI	REMENTS*		
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): 040362 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)														
Medical Device Class, if applicable:														
DUNS:	022490515								Other Temperature Ran	ge Requirement				
Proprietary Name (If Applicable) a		ame: Predn	isone Tablets						(write in)					
Selling Unit NDC:	59746-783-01		Unit of Use NDC:				-59746-783-01-3		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Description: Prednisone 50mg 100ct Tablets Is this product to be shipped to customers on ice? No													
									Is this product to be ship	ped to customers on	dry ice?		No	
Active Ingredient(s):		Prednisone								_				
URL for Additional Product Information: www.cadista.com/products/full-product-list						b. Contact fo	or temperature excursion	questions:	Customer S					
Address:	207 Kiley Drive	www.cauista.co	m/products/run-produc	<u>t-IISt</u>		Address 2:			Name: Number:		(800) 313-4			
City:	Salisbury				State:		Zip: 21801	_	Group E-mail:			.service@ca	adista com	
Key Contact:	Customer Service	9			Email:	customer.service			oroup 2 mam		customer	.sci vice e ce	adista.com	
Phone Number:	(800) 313-4623				Fax:	N/A		c. Special re	gulations for product in	ny states?			No	
Product Therapeutic Classification	on:	Corticosteroid						_	Special returns requiren	ents for this product?			No	
•														
	ADDIT	IONAL PRODUCT IN	IFORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store product (unit of sale) upright?						
The product is?			Is the Product	Direct-Ship Or	nly				Protect product (unit o	sale) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	100 count	e. Shelf life:	. ,	, •			24	Months
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf life at laune	h (if different):				Months
a product kit?		No				Strength:	50mg							
if yes, list NDCs of			FDA Approval Status				T.D. 570			ORDER INFOR	MATION			
component parts reverse numbered?		NI.				Dosage Form:	TABLETS		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present					1	X Bottle		1 bottle of 1		uiiit:	
latex-free?		Yes	Allergens i resent				Round	1	Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape			Ampule		(- 11	
correctional institution block?		Yes				Product Color:	White		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	US		Product Imprin	C 783		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for								Vial Liquid Mu				ich package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered under the Trade Agreements Act (Yes				Vial Powder S Vial Power Mu		48	Each Inner/Cartor	·/Deals	
II Offit Dose, indicate NDC fiere.			Trade Agreements Act (100):	Tes				Other: Write Ir			Case	// aux	
			FOR GENERIC DRUG PR	ODUCTS										
					Au	thorized Generic *I	f Authorized Generic, other			PHARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					Si	ection fields are not applicable	Rec. sell uni	t to customer?		Rx billing u	ınit to pharm	acv:	
II. Generic Equivalent to What Bra	and?:	Deltasone®		_				1	bottle of 100 tablets		Х	Each		
								(Write-in, e.g	g. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT ((DSCSA) INFORI	MATION							Milliliter		
Does supplier meet DSCSA defin		2	Yes	_	GLN:	0359746000004			r	EM AND PACKING I	NEORMATIO	M		
Is product exempt from DSCSA?	ition of manufactu	rer?	No	-	GLN:	0359746000004				EW AND FACKING	INFORMATIO	IN .		
					000	0050740				D:	ions (US msr	mtc \	14-1	0-1
If yes, select exemption: Other exemption - Write in:					GCP:	0359746			Weight Lbs	Dimens Depth	width	mts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If ves was or	riginal product purcha	hazi	Item/Each:					T .	
Is product sold by manufacturer's	s exclusive distrib	utor?	No		direct from m		iocu _	i item/Luem	0.171	1.9	1.9	4	14.44	1
Has FDA granted waiver/exception			No	7	Provide sour	ce manufacturer for r	epackaged product	Box/Carton/	Bundle/				0.00	
If yes, attach documentation fro	m FDA.							Inner Pack:					0.00	
								Case:	8.96	15.5	11.75	5.25	956.16	48
		GT	IN AND HIBCC PRODUCT I	NFORMATION										
Saleable Unit of Measure	,	and a file of the control	LUDOO		OTI	N. 4.4	Helicat Her OTIN 44	Pallet:					0.00	
X Item/Each	•	Saleable Quantity	HIBCC			N-14 59746783013	Unit of Use GTIN-14							
Box/Carton/Bundle/Inner Pack		-			003	39740703013			COST INFORMATION	N		WHO! ESAL	ER USE ONL	γ.
X Case		48			403	59746783011				**				
Pallet					.50			Regular Cos	t		Vendor #:			
								Invoice Cos	(WAC) (\$)	\$32.56	Whsl. Code	e #:		
								11			Fineline Co	ode:		
								As of date:						
1			Attach copy of SAECTY D	ATA CHEET/CDG	2) or non ha-a	rd lotter BACKACE IN	SERT, LABEL AND PHOTO OF	I PRODUCT PACE	ACINC and BARCORE		+			
*Please provide any additional in	formation on nage	2.	Auguroupy or SAFETT DA	ALA SHEET (SD)	or non naza		signated Drop Ship Only.	I NODUCI PACE	Signature:					
	page					p. o ioi De	ga.ou 2. op omp omy.							



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

M/	ATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning?	SDS Hazard Classification Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	No No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:	No No				
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No		Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics				
Is this product regulated for shipment by 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?	No	REMS o Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	r REGISTRY RESTRICTIONS No				
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No No				
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)		REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:		Phone: DEA #: NCPDP#: NPI #:			
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		Comments Registry: Registry Program Contact Name:		Phone:			
ADD'L STORAGE INFORMATION		Comments		FIIOITE.			
Is the Product Controlled Substance? No Controlled Substance Code			ETURN INSTRUCTIONS				
Controlled by State(s)? ARCOS Reportable? Schedule No. No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	No	Contact tel. # if product received damaged: Is product returnable for credit: 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: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?		4				
Comments:							
	ISCELLANEC	OUS 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 fo	r Designated Drop Ship Product	Standard Order Receipt and Processing				
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:				
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:				
F	Name: Phone:	Ships regular ground for 3-10 days receipt:				
Expedited Freight Charg	ges 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:		PO Receipt cut off time:				
Drop Ship miscellaneous fees billed: Comments:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Infor	rmation Required to Process PO:	Return Instructions				
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?				
Mis	scellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				