

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

Version 2021							уре:	Post Launch Change		x Final Version			Date:	7/12	/2021	
			PRODUCT INFORMAT	TION						SPECIAL HA	NDLING AND STOP	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): Outside Room – between 20 and 25 C (68° – 77° F) Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applicable:																
DUNS:	022490515									Other Temperature Range	Requirement					
Proprietary Name (If Applicable)	and Established N	ame: Prednis	one Tablets							(write in)						
Selling Unit NDC:	59746-172-10		Unit of Use NDC:			UPC:	3-5974	46-172-10-7		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Prednisone 5mg	1000ct Tablets								Is this product to be shipp	ed to customers on	ice?		No	1	
	_									Is this product to be shipp				No		
Active Ingredient(s):		Prednisone													1	
	b. Contact for temperature excursion questions:															
URL for Additional Product Inforr					Address 2.			Name: Customer Service								
Address:	207 Kiley Drive					Address 2: MD Zin: 21801			Number:			(800) 313-4623				
City:	Salisbury				State: Email:	MD Zip: 21801 Jackie.Emershaw@jubl.com			Group E-mail:				customer.service@cadista.com			
Key Contact: Phone Number:	Jackie Emershaw (410) 912-3722				Fax:	(215) - 443 - 9646		<u>ibi.com</u>	c. Special regulations for product in any states?					No	1	
		Corticostoroid				(213) - 443 - 3040										
Froduct Therapeutic Classification	Product Therapeutic Classification: Corticosteroid Special returns requirements for this product? No															
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION										ct (unit of sale) upright?				No	1	
	ADDITI	ONALT NODOOT IN		Direct-Ship C) mh.	TRODUCTE	DEOUT	II HOW IN ORMATION]	
The product is? a legend device?		NI.	Is the Product Is the Product	Neither	Tily			1000 count	e. Shelf life:	Protect product (unit of	ale) from light?			No 24	Months	
if yes, enter class #		No	Orphan Drug Status	Neither		Size:		1000 count		Initial shelf life at launch	(if different):			24	Months	
a product kit?		No	Orphan Drug Status					5mg		illidai Sileli ille at ladiloli	(ii dilierenty.				Wionins	
if yes, list NDCs of		140	FDA Approval Status			Strength:					ORDER INFORM	MATION				
component parts						D F		TABLETS								
reverse numbered?		No				Dosage Forn	n:			Unit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							X Bottle		1 bottle of 1	000 tablets			
latex-free?		Yes				Product Sha	pe:	Round		Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)		
preservative-free?		No								Ampule				_		
correctional institution block?		Yes				Product Cold	or:	White		Glass		Minimum o	rder quantity	?	Yes	
opioid? Cannabinoid?		No	Country of Origin	US				TL 172		Tube Vial Liquid Sgl						
If Unit Dose, is item bar coded to	unit does for	No	Country of Origin	03		Product Imp	rint:	1L 1/2		Vial Liquid Multi		If Yes how	many of wh	ch nackane	type?	
hospital scanning?	uriit dose roi		Is this product covered u	nder the						Vial Powder Sql		48	Each	cii package	type:	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		Yes					Vial Power Multi		10	Inner/Cartor	/Pack		
			1							Other: Write In			Case			
			FOR GENERIC DRUG PRO	DDUCTS									_			
									1							
					Au	uthorized Generic		horized Generic, other		Р	HARMACY ORDER	R / BILL UNIT				
I. Orange Book Rating:					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						
									(Write-in, e.g.	1 Vial)	_		Gram			
		DRUG SUPPLY	CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION								Milliliter			
			V							ITE	M AND DAOKING	NEODMATIO	M			
Does supplier meet DSCSA defin Is product exempt from DSCSA?	ition of manufactu	rer?	Yes No	-	GLN:	0359746000004				IIE	M AND PACKING I	NFORWATIO	N .			
*			INO													
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ions (US msr		Volume	Saleable #	
Other exemption - Write in:			No		If you was s	riginal product			Item/Each:		Depth	Width	Height	(Cube)	Pieces	
Is product repackaged? Is product sold by manufacturer's	s avelusiva distrib	utor?	No	-		riginal product irect from mfr?			itterriveach:	0.28	2.4	2.4	4.75	27.36	1	
Has FDA granted waiver/exception			No	-	-	ce manufacturer fo	or renac	ckaged product	Box/Carton/Bu	ındle/						
If yes, attach documentation fro								g	Inner Pack:					0.00		
									Case:	14.47	20.25	14.75	5.13	1532.27	48	
		GTIN	AND HIBCC PRODUCT IN	IFORMATION						14.47	20.25	14.75	5.15	1332.21	40	
									Pallet:					0.00		
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14	-	Unit of Use GTIN-14						0.00		
X Item/Each				59746172107	46172107			COST INITERPRATION			WHOLESALER USE ONLY:					
Box/Carton/Bundle/Inner Pack	48 4035			59746172105	746172105			COST INFORMATION			WHOLESALER USE ONLY:					
X Case Pallet		40			403	03/401/2105	-		Regular Cost			Vendor #:				
Fallet							-		Invoice Cost ()	WAC) (\$)	\$153.19	Whsl. Code	. #·			
											ψ100.10	Fineline Co				
									As of date:			1				
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza			T, LABEL AND PHOTO OF F	PRODUCT PACKA	GING and BARCODE.						
		2						nated Dron Shin Only		Signature:						



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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



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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						
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: 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?						