

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

Version 2021							Гуре:	Post Launch Change		x Final Version			Date:	7/12	/2021	
			PRODUCT INFORMAT	TION						SPECIAL HAN	DLING AND STOR	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 I	Requirement					
Proprietary Name (If Applicable)	and Established Na	ame: Prednis	one Tablets						1	(write in)	•					
Selling Unit NDC:	59746-175-09		Unit of Use NDC:			UPC:	3-5974	46-175-09-2		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Prednisone 20mg	500ct Tablets								Is this product to be shipped	to customers on	ice?		No	1	
										Is this product to be shipped				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			Number:			(800) 313-4623				
City:	Salisbury				State: Email:	мD Jackie.Emersha		Group E-mail:			customer.service@cadista.com					
Key Contact: Phone Number:	Jackie Emershaw (410) 912-3722				Fax:	(215) - 443 - 9646		JDI.COM	c. Special regulations for product in any states?					No	1	
Product Therapeutic Classification		Corticosteroid	Continentaroid			(213) - 443 - 9040			Special returns requirements for this product?			No				
Froduct Therapeutic Classification	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Corticosteroid							,	Special returns requirement	s for this product?			INU		
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION										ct (unit of sale) upright?				No	1	
The manduct is C		J. J. L. HODOOT INI		Direct-Ship C	Only	1 1 1 1 1 1 1			11		la) fram Patro				.i 1	
The product is? a legend device?		NI.	Is the Product Is the Product	Neither	Jrily			500 count	e. Shelf life:	Protect product (unit of sa	le) from light?			No 24	Months	
if yes, enter class #		No	Orphan Drug Status	Neither		Size:		300 count		Initial shelf life at launch (if different):			24	Months	
a product kit?		No	Orphan Drug Status					20mg		illidai sileli ille at ladiloli (i dilierenty.				Wionins	
if yes, list NDCs of		140	FDA Approval Status			Strength:					ORDER INFORM	MATION				
component parts						D F		TABLETS								
reverse numbered?		No				Dosage Form	n:			Unit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							X Bottle		1 bottle of 5	00 tablets			
latex-free?		Yes				Product Sha	ipe:	Round		Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)		
preservative-free?		No								Ampule				_		
correctional institution block?		Yes				Product Cold	or:	Peach		Glass		Minimum o	rder quantity	/?	Yes	
opioid? Cannabinoid?		No	Country of Origin	US				TL 175	-	Tube Vial Liquid Sgl						
If Unit Dose, is item bar coded to	unit dose for	No	Country of Origin	03		Product Imp	rint:	IL 175		Vial Liquid Multi		If Yes how	many of wh	ich package	type?	
hospital scanning?	uriit dose roi		Is this product covered u	nder the						Vial Powder Sql		12	Each	icii package	type:	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		Yes					Vial Power Multi			Inner/Cartor	n/Pack		
			1							Other: Write In			Case			
			FOR GENERIC DRUG PRO	DDUCTS									_			
									7							
					Au	thorized Generic		thorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:			section fields are not applicable			Rec. sell unit to customer? Rx billing unit to				init to pharm	асу:					
II. Generic Equivalent to What Brand?: Deltasone				'					1 bottle of 500 tablets				X Each			
									(Write-in, e.g. 1 Vial)			Gram				
		DRUG SUPPLY	CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION								Milliliter			
			V							ITEN	AND DAOKING I	NEODMATIO	M			
Does supplier meet DSCSA defin Is product exempt from DSCSA?	ition of manufactu	rer?	Yes No	-	GLN:	0359746000004				II EN	AND PACKING I	NFORWATIO	N .			
			INO													
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ions (US msr		Volume	Saleable #	
Other exemption - Write in:			No		K				Ham/Fash	-	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged? Is product sold by manufacturer's	s avelusiva distrib	utor?	No	-		riginal product irect from mfr?			Item/Each:	0.54	2.7	2.7	5.6	40.82	1	
Has FDA granted waiver/exception			No	-	-	ce manufacturer fo	or renac	ckaged product	Box/Carton/Bu	ndle/						
If yes, attach documentation fro								д р	Inner Pack:					0.00		
									Case:	2.7	11.5	8.5	6	586.50	12	
		GTIN	AND HIBCC PRODUCT IN	IFORMATION						2.1	11.5	0.5	0	300.30	12	
									Pallet:					0.00		
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14	_	Unit of Use GTIN-14						0.00		
X Item/Each				59746175092	92			COST INFORMATION			WILLIAM ED HOE ONLY					
Box/Carton/Bundle/Inner Pack		12 4035			59746175090	740475000			COST INFORMATION			WHOLESALER USE ONLY:				
X Case Pallet		12			403	59746175090	-		Regular Cost			Vendor #:				
Fallet									Invoice Cost (V	VAC) (\$)	\$02.30	Whsl. Code	. #·			
									IIIVOIGE COST (V	······································	φ9∠.30	Fineline Co				
									As of date:							
	· <u></u>		Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSER	T, LABEL AND PHOTO OF F	PRODUCT PACKAG	GING and BARCODE.		_				
		2				See new n 3 for				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?						