

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

Version 2021						Introduction 1	Туре:	Post Launch Change		Fi	inal Version			Date:	6/17	/2024
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 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applica	ıble:															
DUNS:	022490515										perature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Prednis	sone Tablets							(write	in)					
Selling Unit NDC: UDI	59746-175-09		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-5974	46-175-09-2		Notes						
										1						
Description: Prednisone 20mg 500ct Tablets Is this product to be shipped to customers on ice? No																
Active Ingredient(s): Is this product to be shipped to customers on dry ice? No								1								
b. Contact for temperature excursion questions:																
URL for Additional Product Information: www.cadista.com/products/full-product-list								Name: C					ervice			
Address: 790 Township Line Road				Address 2:	Suite 3		Number:				(800) 313-4					
City:	Yardley				State:	PA Zip: 19067 customer.service@cadista.com		Group E-mail: customer.service@cadista.co					adista.com			
Key Contact: Phone Number:				Email: Fax:	N/A		adista.com	a Cuanial sas						No	1	
	·			гах.	IN/A			c. Special regulations for product in any states?								
Product Therapeutic Classification: Corticosteroid Special returns requirements for this product? No																
	ADDIT	IONAL PRODUCT INF	FORMATION			PRODUCT	DESCRI	IPTION INFORMATION	d. Store prod	uct (unit of s	sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	inly				a. otoro prod		oduct (unit of sa	la) from light?			No	1
a legend device?		No	Is the Product	Neither	illy			500 count	e. Shelf life:	Frotect pro	oduct (unit of Sa	ile) iroin light?			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:		ooo ooun	0. 0	Initial shelf	f life at launch (if different):				Months
a product kit?	No No				Strength:		20mg									
if yes, list NDCs of			FDA Approval Status			ou engui.			ORDER INFORMATION							
component parts		1				Dosage Form	m:	TABLETS					140	NDO III		
reverse numbered? co-licensed?		No	Allanana Drasant							Unit of Sale	e ottle		1 bottle of 5	NDC selling	unit?	
latex-free?		No Yes	Allergens Present					Round			ox/Carton			g. 1 Box of 1	η Viale)	
preservative-free?		No				Product Sha	ape:	rtound			mpule		(vviite iii, e	.g. 1 Dox 01 1	o viais)	
correctional institution block?		Yes				Product Col		Peach			lass		Minimum o	rder quantity	/?	Yes
opioid?		No				Product Col					ube					
Cannabinoid?		No	Country of Origin	US		Product Imp	orint:	TL 175			ial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		to the month of account to	and another							ial Liquid Multi				ich package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		Yes						ial Powder Sql ial Power Multi		12	Each Inner/Cartor	n/Pack	
Il Offit Dose, indicate NDC here.			Trade Agreements Act (1	AA):	162						ther: Write In			Case	// ack	
			FOR GENERIC DRUG PR	ODUCTS										Guoo		
					Au	thorized Generic	*If Autl	horized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	I. Orange Book Rating: AB section fields are not applicab			n fields are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:											
II. Generic Equivalent to What Bra	and?:	Deltasone®							1 bo	ottle of 500 ta	ablets	1	Х	Each	•	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						(Write-in, e.g. 1 Vial)										
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION									Milliliter		
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0359746000004 ITEM AND PACKING INFORMATION																
Is product exempt from DSCSA?			No	-	JLIT.	33331 40000004					ITEN	. AND I ACKING I	Ortilizatio			
If yes, select exemption:					GCP:	0359746						Dimensi	ions (US msr	nte \	Volume	Saleable #
Other exemption - Write in:					GCF.	0339740					Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	T	If yes, was or	riginal product pur	chased		Item/Each:		0.54	1			<u> </u>	
Is product sold by manufacturer's	s exclusive distrib	utor?	No		direct from m						0.54	2.7	2.7	5.4	39.37	1
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	or repac	kaged product	Box/Carton/B	undle/					0.00	
If yes, attach documentation fro	om FDA.								Inner Pack:							
		CTII	N AND HIBCC PRODUCT II	JEORMATION					Case:		6.84	11.25	8.5	6	573.75	12
		GIII	N AND HIBCC PRODUCT II	W OKWATION					Pallet:							
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14	l unot.						0.00	
X Item/Each		1				59746175092										
Box/Carton/Bundle/Inner Pack										COSTI	NFORMATION			WHOLESAL	ER USE ONL	.Y:
X Case		12			403	59746175090							J			
Pallet							_		Regular Cost Invoice Cost	(M/AC) (\$)		000.00	Vendor #: Whsl. Code			
	_						-		invoice Cost	(AAYC) (2)		\$92.30	Fineline Co			
									As of date:							
													1			
							_						1			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza			T, LABEL AND PHOTO OF F	PRODUCT PACKA	AGING and B	ARCODE.					
*Please provide any additional in	formation on nago					See new n 3 for	r Docian	ated Dron Shin Only		Signaturo:						



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	Inorganic Oxidizer Steroid/Androgen Contact Hazard						
boes the product label bear a OATTOP to warning:	Ornaci Tazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?							
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number							
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry? Website URL:						
e. Inhalation Hazard?	Website ORL.						
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? No	REMS:						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below) Limited Quantity	Provider Name: DEA #: Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry:						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:						
	Comments						
Is the Product Controlled Substance 2	RETURN INSTRUCTIONS						
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	KETORI NOTIONS						
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:	Consider outletions or returns continued for this						
Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:						
- INIGCLELAT							



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 S	nip 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: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?