

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

Version 2021						Introduction Type	: Post Launch Change		x Fin	al Version			Date:	6/17	/2024
			PRODUCT INFORMA	TION					:	SPECIAL HAN	DLING AND STOR	AGE 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): 040189						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicable:															
DUNS:	022490515							_	Other Tempe	erature Range I	Requirement				
Proprietary Name (If Applicable) a		ame: Methy	Iprednisolone Tablets						(write in	n)					
Selling Unit NDC:	59746-003-14		Unit of Use NDC:				9746-003-14-2		Notes						
UDI			CVX Code:			MVX Code:		1							
Description: Methylprednisolone 16mg 50ct Tablets Is this product to be shipped to customers on ice? No															
Is this product to be shipped to customers on dry ice?															
Active Ingredient(s): Methylprednisolone b. Contact for temperature excursion questions:															
URL for Additional Product Information: www.cadista.com/products/full-product-list								excursion qu	estions:	Customer S					
Address:	790 Township Lir		m/products/full-produc	t-IIST		Address 2: Su	ite 325	+	Name: Number:			(800) 313-46			
City:	Yardley											ner.service@cadista.com			
Key Contact:	Customer Service							<u>easterner service (e caustateoni</u>							
Phone Number:	(800) 313-4623				Fax:	N/A		c. Special re	egulations for p	product in any	states?			No	1
Product Therapeutic Classification	on:	Corticosteroid						-	Special retur	ns requirement	ts for this product?			No	
openia in an a square in an a process.									1						
	ADDIT	IONAL PRODUCT IN	IFORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store pro	duct (unit of sa	ale) upright?				No	
The product is?			Is the Product	Direct-Ship Only					Protect prod	duct (unit of sa	ale) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	50 count	e. Shelf life:	•	•	, ,			24	Months
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf I	life at launch (if different):				Months
a product kit?		No				Strength:	16mg								
if yes, list NDCs of			FDA Approval Status			J					ORDER INFORM	IATION			
component parts reverse numbered?		N.				Dosage Form:	TABLETS		Unit of Sale			What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present						X Bot	HIO		1 bottle of 5		unit:	
latex-free?		Yes	Allergens i resent				Oval, Quadrisected			x/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape:				pule		(g	,	
correctional institution block?		Yes				Product Color:	White		Gla			Minimum o	der quantity	?	Yes
opioid?		No				Froduct Color.			Tut						
Cannabinoid?		No	Country of Origin	US		Product Imprint:	TL 003			ıl Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for									I Liquid Multi				ch package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered under the Trade Agreements Act (I Powder Sql		24	Each Inner/Cartor	/De al-	
II Offit Dose, indicate NDC fiere.			Trade Agreements Act (IAA): Tes						ner: Write In			Case	/rack	
			FOR GENERIC DRUG PR	ODUCTS									1		
												1			
					Aut	horized Generic *If	Authorized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AB					sec	ction fields are not applicable	Rec. sell uni	it to customer?	?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra	and?:	Medrol®		_				1	bottle of 50 tab	lets		Х	Each		
		`						(Write-in, e.g	g. 1 Vial)		_		Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT ((DSCSA) INFORMATION	ON								Milliliter		
Does supplier meet DSCSA defin		2	Yes	GLN:		0359746000004				ITEA	AND PACKING IN	JEORMATIO	N .		
Is product exempt from DSCSA?		rerr	No	GLN:		0359746000004				IIEN	I AND FACKING II	NFORMATIO	1		
			140			2000010		-			Dimensi	(110	-4- \		
If yes, select exemption: Other exemption - Write in:				GCP:		0359746		1	,	Weight Lbs.	Dimensi Depth	ons (US msn Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No	If yes	was ori	ginal product purchas	has	Item/Each:			1				
Is product sold by manufacturer's	s exclusive distrib	utor?	No		t from m					0.07	1.8	1.8	3	9.72	1
Has FDA granted waiver/exception			No	Provi	de sourc	e manufacturer for re	packaged product	Box/Carton/	Bundle/					0.00	
If yes, attach documentation fro	m FDA.							Inner Pack:						0.00	
								Case:		2.06	11	7.5	4.25	350.63	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION											
Saleable Unit of Measure		and the contract	LUDOO		OTIN	1.4.4	Helicat Her OTINI 44	Pallet:						0.00	
X Item/Each	:	Saleable Quantity	HIBCC		GTIN	N-14 59746003142	Unit of Use GTIN-14								
Box/Carton/Bundle/Inner Pack		-			0035	757 40005 142			COST.IN	FORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			4035	59746003140									
Pallet								Regular Cos	st			Vendor #:			
								Invoice Cost	t (WAC) (\$)		\$124.23	Whsl. Code	#:		
								11				Fineline Co	de:		
								As of date:				Į.			
								11							
1			Attach copy of SAECTY D	\TA CHEET (CDC)	on horse	d latter BACKACE INC	SERT, LABEL AND PHOTO OF	DECULICE BACK	(ACINC and DA	PCODE					
*Please provide any additional in	formation on nage	2	Audul copy of SAFETY DA	AIV OUEE! (ODO) OLU	ion nazar		signated Drop Ship Only.	I NODUCI PACK	Signature:	INCODE.					
	paye	- -				- 30 p. 0 101 Dea	D. OF Jinp Jiny.		J.guturo.						



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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?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive Inorganic Oxidizer						
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							



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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?