

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

Version 2021						Introduction Type:	Post Launch Change	X				Date:	7/12/	2021
			PRODUCT INFORMA	TION					SPECIAL HANI	DLING AND STOR	AGE REQUI	EMENTS*		
Company Name:	Jubilant Cadista	Pharmaceuticals Inc.				Application:	ANDA	a. Temperature - Inc	dicate the USP tempe	rature range for t	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 040189									erature Range	Controlled Room -	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ible:		·						=					
DUNS:	022490515							Other	Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established N	ame: Methy	Iprednisolone Tablets						(write in)	·				
Selling Unit NDC:	59746-002-04		Unit of Use NDC:			UPC: 3-597	46-002-04-6	Notes						
UDI			CVX Code:			MVX Code:								
Description:	Methylprednisolo	lo thio	product to be shipped	l to quotomoro on i	202	1	No							
Description.	Metrypredrisolo	ne only 25ct Tablets							product to be shipped product to be shipped				No	
Active Ingredient(s):		Methylprednisolone	<u> </u>					15 11115	product to be shipped	i to customers on c	ily ice:	I.	140	
Active ingredient(s).		Wearypreamsolone	•					b. Contact for tempe	erature excursion que	estions.				
URL for Additional Product Inforn	mation:	www cadista co	m/products/full-produc	t-list				Name			Customer Se	rvice		
Address:	207 Kiley Drive	WWW.caa.starco	, p. oudoto, ran produc	<u>c 110 c</u>		Address 2:		Numb			(800) 313-46			
City:	Salisbury				State:	MD Zip:	21801		p E-mail:			ervice@ca	dista.com	
Key Contact:	Jackie Emershav	V			Email:	Jackie.Emershaw@j								
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646		c. Special regulation	ns for product in any	states?		[No	
Product Therapeutic Classification	on:	Corticosteroid							al returns requirement				No	
Spotal value (squission to the product														
	ADDIT	ONAL PRODUCT IN	IFORMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store product (un	it of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Only				Prote	ct product (unit of sa	le) from light?		i	No	
a legend device?		No	Is the Product	Neither			25 count	e. Shelf life:	or product (unit or sa	ic, iroin iigiit.			24	Months
if yes, enter class #		INO	Orphan Drug Status			Size:	20 obunt		shelf life at launch (i	f different)				Months
a product kit?		No	orpinan Drug otatao				8mg		onon mo at launon (i					
if yes, list NDCs of		110	FDA Approval Status			Strength:				ORDER INFORM	IATION			
component parts						B	TABLETS							
reverse numbered?		No				Dosage Form:		Unit o	of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					Х	Bottle		1 bottle of 2	tablets		
latex-free?		Yes	_			Product Shape:	Oval		Box/Carton		(Write-in, e.	g. 1 Box of 10	Vials)	
preservative-free?		No				Froduct Snape.			Ampule					
correctional institution block?		Yes				Product Color:	White		Glass		Minimum o	der quantity	?	Yes
opioid?		No				rioduct color.			Tube					
Cannabinoid?		No	Country of Origin	US		Product Imprint:	TL 002		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					oudot impinio			Vial Liquid Multi			many of which	ch package t	ype?
hospital scanning?			Is this product covered u						Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)? Yes					Vial Power Multi			Inner/Carton/	Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
									BU	ARMACY ORDER	/ DULL LINUT			
				_	Au		thorized Generic, other on fields are not applicable			ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					36011	on neids are not applicable	Rec. sell unit to cus				nit to pharma	ıcy:	
II. Generic Equivalent to What Bra	and?:	Medrol							25 tablets		Х	Each		
		DRUG CURRI	Y CHAIN SECURITY ACT (Decea) INFORMAT	ION			(Write-in, e.g. 1 Vial)				Gram Milliliter		
		DRUG SUFFL	T CHAIN SECURITT ACT	D3C3A) INFORMAT	ION							wiiiiiitei		
Does supplier meet DSCSA defini	ition of manufactu	irer?	Yes	GLN	:	0359746000004			ITEM	AND PACKING IN	IFORMATIO			
Is product exempt from DSCSA?			No											
If yes, select exemption:				GCF		0359746		i		Dimensi	ons (US msn	its)	Volume	Saleable #
Other exemption - Write in:				GCF	•			'	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	If ve	s. was or	iginal product		Item/Each:						
			No			rect from mfr?			0.06	1.9	1.9	4	14.44	1
Is product sold by manufacturer's	s exclusive distrib	utor?	INO		ride sour	ce manufacturer for repa	ckaged product	Box/Carton/Bundle/					0.00	
Has FDA granted waiver/exceptio			No	Prov									0.00	
	on/exemption for p			Prov				Inner Pack:						24
Has FDA granted waiver/exceptio	on/exemption for p	roduct?	No					Inner Pack: Case:	1.8	11	7.5	4.25	350.63	
Has FDA granted waiver/exceptio	on/exemption for p	roduct?						Case:	1.8	11	7.5	4.25	350.63	
Has FDA granted waiver/exceptio If yes, attach documentation fro	on/exemption for pom FDA.	roduct?	No N AND HIBCC PRODUCT I			NAA	Unit of Line OTAL 44		1.8	11	7.5	4.25	0.00	
Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure	on/exemption for pom FDA.	roduct?	No		GTII		Unit of Use GTIN-14	Case:	1.8	11	7.5	4.25		
Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each	on/exemption for pom FDA.	roduct?	No N AND HIBCC PRODUCT I		GTII	N-14 59746002046	Unit of Use GTIN-14	Case: Pallet:		11			0.00	٧٠
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	on/exemption for pom FDA.	GTI Saleable Quantity	No N AND HIBCC PRODUCT I		GTII 0038	59746002046	Unit of Use GTIN-14	Case: Pallet:	1.8 OST INFORMATION	11		4.25 WHOLESALE	0.00	Y:
Has FDA granted waiver/exception of yes, attach documentation from the same of	on/exemption for pom FDA.	roduct?	No N AND HIBCC PRODUCT I		GTII 0038		Unit of Use GTIN-14	Case: Pallet:		11			0.00	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	on/exemption for pom FDA.	GTI Saleable Quantity	No N AND HIBCC PRODUCT I		GTII 0038	59746002046	Unit of Use GTIN-14	Case: Pallet: CG Regular Cost	DST INFORMATION		Vendor #:	WHOLESALE	0.00	Y:
Has FDA granted waiver/exception of yes, attach documentation from the same of	on/exemption for pom FDA.	GTI Saleable Quantity	No N AND HIBCC PRODUCT I		GTII 0038	59746002046	Unit of Use GTIN-14	Case: Pallet:	DST INFORMATION	\$40.21	Vendor #: Whsl. Code	WHOLESALE	0.00	Y:
Has FDA granted waiver/exception of yes, attach documentation from the same of	on/exemption for pom FDA.	GTI Saleable Quantity	No N AND HIBCC PRODUCT I		GTII 0038	59746002046	Unit of Use GTIN-14	Case: Pallet: Co Regular Cost Invoice Cost (WAC)	DST INFORMATION		Vendor #:	WHOLESALE	0.00	Y:
Has FDA granted waiver/exception of yes, attach documentation from the same of	on/exemption for pom FDA.	GTI Saleable Quantity	No N AND HIBCC PRODUCT I		GTII 0038	59746002046	Unit of Use GTIN-14	Case: Pallet: CG Regular Cost	DST INFORMATION		Vendor #: Whsl. Code	WHOLESALE	0.00	Y:
Has FDA granted waiver/exception of yes, attach documentation from the same of	on/exemption for pom FDA.	GTI Saleable Quantity	No N AND HIBCC PRODUCT I		GTII 0038	59746002046	Unit of Use GTIN-14	Case: Pallet: Co Regular Cost Invoice Cost (WAC)	DST INFORMATION		Vendor #: Whsl. Code	WHOLESALE	0.00	Y:
Has FDA granted waiver/exception of yes, attach documentation from the same of	on/exemption for pom FDA.	GTI Saleable Quantity	NO N AND HIBCC PRODUCT I HIBCC	NFORMATION	GTII 0038 4038	59746002044	Unit of Use GTIN-14	Case: Pallet: Co Regular Cost Invoice Cost (WAC) As of date:	DST INFORMATION (\$)		Vendor #: Whsl. Code	WHOLESALE	0.00	Y:



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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:	Overnight receipt available:					
Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	PO Receipt cut off time: 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, 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:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Information Required to Process PO:	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?					