



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

Version 2021

Introduction Type: Post Launch Change

Final Version

Date: 6/17/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 040189 Medical Device Class, if applicable: DUNS: 022490515 Proprietary Name (If Applicable) and Established Name: Methylprednisolone Tablets Selling Unit NDC: 59746-003-14 Unit of Use NDC: UPC: 3-59746-003-14-2 UDI CVX Code: MXV Code:		Application: ANDA Description: Methylprednisolone 16mg 50ct Tablets Active Ingredient(s): Methylprednisolone URL for Additional Product Information: www.cadista.com/products/full-product-list Address: 790 Township Line Road City: Yardley Key Contact: Customer Service Phone Number: (800) 313-4623 Product Therapeutic Classification: Corticosteroid		Address 2: Suite 325 State: PA Zip: 19067 Email: customer.service@cadista.com Fax: N/A		a. Temperature – Indicate the USP temperature range for this product. Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in) Notes Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No																																
Is the Product... Direct-Ship Only <input type="checkbox"/> Is the Product... Neither <input type="checkbox"/> Orphan Drug Status FDA Approval Status Allergens Present Country of Origin <input type="text" value="US"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes		Size: 50 count Strength: 16mg Dosage Form: TABLETS Product Shape: Oval, Quadrisected Product Color: White Product Imprint: TL 003		b. Contact for temperature excursion questions: Name: Customer Service Number: (800) 313-4623 Group E-mail: customer.service@cadista.com c. Special regulations for product in any states? <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No d. Store product (unit of sale) upright? <input type="checkbox"/> No Protect product (unit of sale) from light? <input type="checkbox"/> No e. Shelf life: <input type="checkbox"/> 24 Months Initial shelf life at launch (if different): <input type="checkbox"/> Months																																		
ADDITIONAL PRODUCT INFORMATION				ORDER INFORMATION																																		
The product is? a legend device? <input type="checkbox"/> No if yes, enter class # a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No latex-free? <input type="checkbox"/> Yes preservative-free? <input type="checkbox"/> No correctional institution block? <input type="checkbox"/> Yes opioid? <input type="checkbox"/> No Cannabinoid? <input type="checkbox"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> If Unit Dose, indicate NDC here:		Is the Product... Direct-Ship Only <input type="checkbox"/> Is the Product... Neither <input type="checkbox"/> Orphan Drug Status FDA Approval Status Allergens Present Country of Origin <input type="text" value="US"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes		Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In		What is the NDC selling unit? <input type="text" value="1 bottle of 50 tablets"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? <input type="text" value="24"/> Each <input type="text"/> Inner/ Carton/Pack <input type="text"/> Case																																
FOR GENERIC DRUG PRODUCTS				PHARMACY ORDER / BILL UNIT																																		
I. Orange Book Rating: <input type="text" value="AB"/> II. Generic Equivalent to What Brand?: <input type="text" value="Medrol®"/>		<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable		Rec. sell unit to customer? <input type="text" value="1 bottle of 50 tablets"/> (Write-in, e.g. 1 Vial)		Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																																
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				ITEM AND PACKING INFORMATION																																		
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes Is product exempt from DSCSA? <input type="checkbox"/> No If yes, select exemption: Other exemption - Write in: Is product repackaged? <input type="checkbox"/> No Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No If yes, attach documentation from FDA.		GLN: 0359746000004 GCP: 0359746 If yes, was original product purchased direct from mfr? <input type="checkbox"/> Provide source manufacturer for repackaged product		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Item/Each:</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2">Saleable # Pieces</th> </tr> <tr> <th>Depth</th> <th>Width</th> <th>Height</th> </tr> </thead> <tbody> <tr> <td>Box/Carton/Bundle/Inner Pack:</td> <td></td> <td></td> <td></td> <td></td> <td>0.00</td> <td></td> </tr> <tr> <td>Case:</td> <td>2.06</td> <td>11</td> <td>7.5</td> <td>4.25</td> <td>350.63</td> <td>24</td> </tr> <tr> <td>Pallet:</td> <td></td> <td></td> <td></td> <td></td> <td>0.00</td> <td></td> </tr> </tbody> </table>		Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	Depth	Width	Height	Box/Carton/Bundle/Inner Pack:					0.00		Case:	2.06	11	7.5	4.25	350.63	24	Pallet:					0.00			
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*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship 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
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 - Is the product a CA Prop 65 carcinogen? No
 - Is the product a CA Prop 65 reproductive toxicant? No
 - Does the product label bear a CA Prop 65 warning? No

- c. Contact Hazard? No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger No
- Cargo No
- Passenger & Cargo No

Is this a reportable quantity? No

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- No (if yes, identify method below)
- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? No Yes
- Controlled Substance Code
- Controlled by State(s)? No Yes
- Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes
- If yes, indicate which:
- Schedule No.
- Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required No

Limited Distribution Requirement No

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#:

NPI #:

Comments

Registry:

Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

