



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

Version 2021 Introduction Type:  Post Launch Change  Final Version Date: 6/9/2023

## PRODUCT INFORMATION

**Company Name:** Jubilant Cadista Pharmaceuticals Inc. **Application:** ANDA

**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:** 59746-001-03 **Unit of Use NDC:** **UPC:** 3-59746-001-03-2

**UDI** **CVX Code:** **MXV Code:**

**Description:** Methylprednisolone 4mg 21ct Dose Pack

**Active Ingredient(s):** Methylprednisolone

**URL for Additional Product Information:** [www.cadista.com/products/full-product-list](http://www.cadista.com/products/full-product-list)

**Address:** 207 Kiley Drive **Address 2:**

**City:** Salisbury **State:** MD **Zip:** 21801

**Key Contact:** Customer Service **Email:** [customer.service@cadista.com](mailto:customer.service@cadista.com)

**Phone Number:** (800) 313-4623 **Fax:** N/A

**Product Therapeutic Classification:** Corticosteroid

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**a. Temperature – Indicate the USP temperature range for this product.**

Temperature Range:

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice?  No

Is this product to be shipped to customers on dry ice?  No

**b. Contact for temperature excursion questions:**

**Name:** Customer Service

**Number:** (800) 313-4623

**Group E-mail:** [customer.service@cadista.com](mailto:customer.service@cadista.com)

**c. Special regulations for product in any states?**

Special returns requirements for this product?  No

**d. Store product (unit of sale) upright?**  No

Protect product (unit of sale) from light?  No

**e. Shelf life:**

Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?  No

If yes, enter class # a product kit?  No

If yes, list NDCs of component parts reverse numbered?  No

co-licensed?  No

latex-free?  Yes

preservative-free?  No

correctional institution block?  Yes

opioid?  No

Cannabinoid?  No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

**Is the Product... Direct-Ship Only**

**Is the Product... Unit of Use**

**Orphan Drug Status**

**FDA Approval Status**

**Allergens Present**

**Country of Origin**

Is this product covered under the Trade Agreements Act (TAA)?  Yes

## PRODUCT DESCRIPTION INFORMATION

**Size:** 21 count

**Strength:** 4mg

**Dosage Form:** TABLETS

**Product Shape:** Oval, Quartersected

**Product Color:** White

**Product Imprint:** TL 001

## ORDER INFORMATION

**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?**   
(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes

**If Yes, how many of which package type?**

|                                 |                   |
|---------------------------------|-------------------|
| <input type="text" value="72"/> | Each              |
| <input type="text"/>            | Inner/Carton/Pack |
| <input type="text"/>            | Case              |

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:**

**II. Generic Equivalent to What Brand?:**

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?**   
(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

Does supplier meet DSCSA definition of manufacturer?  Yes

Is product exempt from DSCSA?  No

If yes, select exemption:

Other exemption - Write in:

Is product repackaged?  No

Is product sold by manufacturer's exclusive distributor?  No

Has FDA granted waiver/exception/exemption for product?  No

If yes, attach documentation from FDA.

**GLN:** 0359746000004

**GCP:** 0359746

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product:

## ITEM AND PACKING INFORMATION

| Item/Each:                    | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
|                               |             | Depth                  | Width | Height |               |                   |
| Box/Carton/Bundle/Inner Pack: | 0.04        | 0.75                   | 4.75  | 3.75   | 13.36         | 1                 |
| Case:                         | 4.2         | 15.81                  | 14.88 | 5.5    | 1293.89       | 72                |
| Pallet:                       |             |                        |       |        | 0.00          |                   |

## GTIN AND HIBCC PRODUCT INFORMATION

| Saleable Unit of Measure                              | Saleable Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
|-------------------------------------------------------|-------------------|-------|----------------|---------------------|
| <input checked="" type="checkbox"/> Item/Each         | 1                 |       | 00359746001032 | 00359746001032      |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |                   |       |                |                     |
| <input checked="" type="checkbox"/> Case              | 72                |       | 40359746001030 |                     |
| <input type="checkbox"/> Pallet                       |                   |       |                |                     |

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) (\$)**

As of date:

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**



# 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?  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  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  Contact Hazard

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

Is the product a NIOSH hazardous drug? If yes, indicate which:  No

### 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:



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Version 2021

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:<br>a. EDI <input type="checkbox"/><br>b. Autofax <input type="checkbox"/><br>c. Fax <input type="checkbox"/><br>d. Phone only <input type="checkbox"/><br>e. Supplier Web Site only <input type="checkbox"/><br>Minimum Order Quantity: <input type="text"/><br>Supplier's Customer Service Number: <input type="text"/><br>Contracted 3PL company / contact #: <input type="text"/><br>Name: <input type="text"/><br>Phone: <input type="text"/><br>Fax Number: <input type="text"/><br>Fax Number: <input type="text"/><br>Phone No.: <input type="text"/><br>Site Address: <input type="text"/> | <b>Purchase order daily receipt cut off time by supplier</b><br>Cut off time: <input type="text"/><br>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days<br>Ships same day for next day receipt: <input type="checkbox"/><br>Ships for second day receipt: <input type="checkbox"/><br>Ships regular ground for 3-10 days receipt: <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Expedited Freight Charges or Other Designated Drop Ship Fees:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Overnight and Priority Overnight PO Processing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Expedited freight fees billed with each order: <input type="text"/><br>Drop Ship service fee billed with each order: <input type="text"/><br>Drop Ship miscellaneous fees billed: <input type="text"/><br>Comments: <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                               | <b>Overnight receipt available:</b> <input type="checkbox"/><br><b>PO Receipt cut off time:</b> <input type="text"/><br>Days of week overnight is available:<br><input type="checkbox"/> Monday<br><input type="checkbox"/> Tuesday<br><input type="checkbox"/> Wednesday<br><input type="checkbox"/> Thursday<br><input type="checkbox"/> Friday<br><b>Priority Overnight receipt available:</b> <input type="checkbox"/><br>PO Receipt Cut off time: <input type="text"/><br><b>Saturday Overnight receipt available:</b> <input type="checkbox"/><br>PO Receipt Cut off time: <input type="text"/><br>Order receipt method: <input type="text"/><br>Phone: <input type="text"/> Phone #: <input type="text"/><br>Fax: <input type="text"/> Fax #: <input type="text"/><br>EDI: <input type="text"/><br>Overnight Fees apply: <input type="checkbox"/><br>Other fees apply: <input type="checkbox"/> |
| Class of Trade Restriction:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/><br>Restricted to retail pharmacy only: <input type="checkbox"/><br>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/><br>Restricted from US territories? (explain in comments) <input type="checkbox"/><br>Comments: <input type="text"/>                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Other Data Information Required to Process PO:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Return Instructions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Patient Procedure Date: <input type="text"/><br>Physician Name: <input type="text"/><br>Physician/Clinic Phone #: <input type="text"/><br>Physician State License #: <input type="text"/><br>Physician/Clinic DEA #: <input type="text"/><br>Physician/Clinic Specialty: <input type="text"/>                                                                                                                                                                                                                                                                                                                                          | Contact # if product is received damaged: <input type="text"/><br>Is product returnable for credit: <input type="checkbox"/><br>URL/Link to returns policy: <input type="text"/><br>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/><br>If so, which states? Other requirements? Comments? <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Miscellaneous Notes:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ADDITIONAL INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Is product order for scheduled patient procedure? <input type="checkbox"/><br>Is product order for restocking purposes? <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |