



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Pre-Launch Change Post-Launch Change Final Version

Date: 4/30/20

| PRODUCT INFORMATION | |
|---|--|
| Company Name: | Jubilant Cadista Pharmaceuticals Inc. |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | A40189 |
| DUNS: | 022490515 |
| Proprietary Name (If Applicable) and Established Name: | Methylprednisolone Tablets |
| Selling Unit NDC: | 59746-0002-04 |
| Individual Unit NDC: | |
| UPC: | 3-59746-002-04-6 |
| CVX Code: | |
| MXV Code: | |
| Description: | Methylprednisolone 8mg Tablets 25ct. |
| Active Ingredient(s): | Methylprednisolone |
| URL for Additional Product Information: | www.cadista.com |
| Address: | 207 Kiley Drive Salisbury Key Contact: Jackie Emershaw Phone Number: (410) 912-3722 |
| State: | MD |
| Zip: | 21801 |
| Email: | Jackie.Emershaw@cadista.com |
| Fax: | (215) 443-9646 |
| Product Therapeutic Classification: | |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS | |
|---|---|
| a. Temperature – Indicate the USP temperature range for this product. | |
| Temperature Range | Controlled Room – between 20 and 25 C (68° – 77°) |
| Other Temperature Range Requirement (write in) | |
| 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 Support |
| Number: | (800) 313-4623 |
| Group E-mail: | |
| c. Special regulations for product in any states? | No |
| 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): | 24 Months |

| ADDITIONAL PRODUCT INFORMATION | |
|---|-----|
| Is the Product... a legend device? | Yes |
| reverse numbered? | No |
| co-licensed? | No |
| Is the Product... Direct-Ship Only? | |
| Is the Product... Direct-Ship Only? | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | |
| If Unit Dose NDC, indicate NDC here: | |
| Country of Origin | |
| Is this product covered under the Trade Agreements Act (TAA)? | |

| PRODUCT DESCRIPTION INFORMATION | |
|---------------------------------|--------|
| Size: | 25ct |
| Strength: | 8mg |
| Dosage Form: | TAB |
| Product Shape: | Oval |
| Product Color: | White |
| Product Imprint: | TL 002 |

| ORDER INFORMATION | |
|--|---|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | 1 Case of 24 Bottles |
| <input type="checkbox"/> Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Ampule | |
| <input type="checkbox"/> Glass | Minimum order quantity? Yes |
| <input type="checkbox"/> Tube | |
| <input type="checkbox"/> Vial Liquid Sgl | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Liquid Multi | 24 Each |
| <input type="checkbox"/> Vial Powder Sgl | Inner/ Carton/Pack |
| <input type="checkbox"/> Vial Power Multi | Case |
| <input type="checkbox"/> Other: Write In | |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | AB |
| II. Generic Equivalent to What Brand?: | Medrol® |
| <input type="checkbox"/> Authorized Generic | *If Authorized Generic, other section fields are not applicable |

| PHARMACY ORDER / BILL UNIT | |
|-----------------------------|------------------------------|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| (Write-in, e.g. 1 Vial) | Each |
| | Gram |
| | 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 |
| GLN: | 0359746000004 |
| If Yes, was original product purchased direct from mfr? | |
| If yes, attach documentation from FDA. | |

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|--------|-------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width | | |
| Box/Carton/Bundle/Inner Pack: | 0.06 | 1.80 | 3.0 | 1.80 | 9.72 | 1 |
| Case: | 1.80 | 11.00 | 4.25 | 7.50 | 350.63 | 24 |
| Pallet: | | | | | 0 | |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | |
|---|--|----------|----------------|
| Serialized? | Yes | | |
| If not, when? | | | |
| Items aggregated? | | | |
| Level | Saleable Unit | Quantity | GTIN-14 |
| <input checked="" type="checkbox"/> Item | <input checked="" type="checkbox"/> 2D | 1 | 00359746002046 |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack | <input type="checkbox"/> 2D | | |
| <input checked="" type="checkbox"/> Case | <input checked="" type="checkbox"/> 2D | 24 | 40359746002044 |
| <input type="checkbox"/> Pallet | <input type="checkbox"/> 2D | | |
| | <input type="checkbox"/> 2D | | |
| | <input type="checkbox"/> 2D | | |
| | <input type="checkbox"/> 2D | | |
| | <input type="checkbox"/> 2D | | |
| | <input type="checkbox"/> 2D | | |
| | <input type="checkbox"/> 2D | | |
| | <input type="checkbox"/> 2D | | |
| | <input type="checkbox"/> 2D | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------------------|---------|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | \$40.21 | Whsl. Code #: | |
| Federal Excise Tax Per Unit of Sale | | Fineline Code: | |
| As of date: | | | |

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? No
 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? No
 (If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? No
 (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?

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

Passenger

Cargo

Passenger & Cargo

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

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:

Is it a scheduled listed chemical product?

CLASS OF TRADE RESTRICTION:

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

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

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

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
 If Yes, is it managed with a pharmacy registry?
 Website URL:

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

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:
 Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

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:



Standard Pharmaceutical Product Information (Page 3)

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