

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

|   |  |   |                                 |                              |   | Introduction Type:  | Post Launch Change           |   | x Final Version  |                      |   | Date:                                    | 0/9/2                            | 2023        |
|---|--|---|---------------------------------|------------------------------|---|---|------------------------------|---|--|----------------------|---|--|----------------------------------|-------------|
|   |  |   | PRODUCT INFORMA                 | TION                         |   |   |                              |   | SPECIAL HAN  | DLING AND STOR       | AGE REQUIF                                | REMENTS*                                 |                                  |             |
| Company Name: Jubilant Cadista Pharmaceuticals Inc. ANDA  |  |   |                                 |                              |   | a. Temperature – Indicate the USP temperature range for this product.                   |                              |   |  |                      |   |  |                                  |             |
| Application Number for NDA/A  | NDA/BLA (drug); P                                    | MA/510(k)(med device  | e):                             | 040189                       |   |   |                              |   | Temperature Range  | Controlled Room -    |   | and 25 C (68                             | ° – 77° F)                       | - 1         |
| Medical Device Class, if applica  | able:  |   |                                 |                              |   |   |                              | 1   |  |                      |   |  |                                  |             |
| DUNS:   | 022490515  |   |                                 |                              |   |   |                              |   | Other Temperature Range                                    | Requirement          |   |  |                                  |             |
| Proprietary Name (If Applicable)  |  | ame: Methylr  | prednisolone Tablets            |                              |   |   |                              | I   | (write in)   |                      |   |  |                                  |             |
| Selling Unit NDC:   | 59746-001-06   |   | Unit of Use NDC:                |                              |   |   | 746-001-06-3                 |   | Notes  |                      |   |  |                                  |             |
| UDI   |  |   | CVX Code:                       |                              |   | MVX Code:   |                              | 1   |  |                      |   |  |                                  |             |
| Description:  | Methylprednisolo                                     | ne 4mg 100ct Tablets  |                                 |                              |   |   |                              | Ţ   | Is this product to be shippe                               | d to customers on ic | e?  |  | No                               |             |
|   |  |   |                                 |                              |   |   |                              |   | Is this product to be shipped                              | d to customers on d  | ry ice?                                   |  | No                               |             |
| Active Ingredient(s):   |  | Methylprednisolone  |                                 |                              |   |   |                              |   |  | _                    |   |  |                                  |             |
| UDI des Additional Basedon Inform   |  |   |                                 | s Pas                        |   |   |                              | b. Contact fo   | r temperature excursion qu                                 | estions:             | 0   |  |                                  |             |
| URL for Additional Product Inform<br>Address:   | 207 Kiley Drive                                      | www.cadista.com   | m/products/full-product         | <u>t-list</u>                |   | Address 2:  |                              | -   | Name:<br>Number:   |                      | Customer Se<br>(800) 313-46               |  |                                  |             |
| City:   | Salisbury  |   |                                 |                              | State:                                      |   | 21801                        |   | Group E-mail:  |                      | customer.                                 |  | dicta com                        |             |
| Key Contact:  | Customer Service                                     | a   |                                 |                              | Email:                                      | customer.service@c  |                              |   | Group L-mail.  |                      | <u>customer.</u>                          | sei vice wca                             | uista.com                        |             |
| Phone Number:   | (800) 313-4623                                       |   |                                 |                              | Fax:  | N/A   | .adista.com                  | c. Special red  | gulations for product in any                               | states?              |   |  | No                               | 1           |
| Product Therapeutic Classification  |  | Corticosteroid  |                                 |                              |   |   |                              | j   | Special returns requirement                                |                      |   |  | No                               | 1           |
| l rouge merupouno encompani   |  |   |                                 |                              |   |   |                              |   | opoolal rotarrio roquirorriorr                             | o for ano product.   |   |  |                                  | 1           |
|   | ADDIT  | IONAL PRODUCT INF   | FORMATION                       |                              |   | PRODUCT DESCR   | RIPTION INFORMATION          | d. Store prod   | duct (unit of sale) upright?                               |                      |   |  | No                               | 1           |
| The product is?   |  |   | Is the Product                  | Direct-Ship Only             |   |   |                              |   | Protect product (unit of sa                                | le) from light?      |   |  | No                               | i           |
| a legend device?  |  | No  | Is the Product                  | Neither                      | _   |   | 100 count                    | e. Shelf life:  | Frotect product (unit of Sa                                | ile) iroin light?    |   |  | 24                               | Months      |
| if yes, enter class #   |  | 140   | Orphan Drug Status              |                              |   | Size:   | 100 count                    | C. Onen me.   | Initial shelf life at launch (                             | if different)        |   |  | 24                               | Months      |
| a product kit?  |  | No  |                                 |                              |   |   | 4mg                          |   |  |                      |   |  |                                  | ,           |
| if yes, list NDCs of  |  |   | FDA Approval Status             |                              |   | Strength:   |                              |   |  | ORDER INFORM         | ATION                                     |  |                                  |             |
| component parts   |  |   |                                 |                              |   | Dosage Form:  | TABLETS                      |   |  |                      |   |  |                                  |             |
| reverse numbered?   |  | No  |                                 |                              |   | Dosage Form.  |                              |   | Unit of Sale   |                      | What is the                               |  | unit?                            |             |
| co-licensed?  |  | No  | Allergens Present               |                              |   |   |                              |   | X Bottle   |                      | 1 bottle of 10                            |  |                                  |             |
| latex-free?   |  | Yes   |                                 |                              |   | Product Shape:  | Oval, Quartersected          |   | Box/Carton   |                      | (Write-in, e.                             | g. 1 Box of 1                            | J Vials)                         |             |
| preservative-free?  |  | No  |                                 |                              |   |   | NAME II -                    |   | Ampule   |                      |   |  | •                                | V           |
| correctional institution block? opioid?   |  | Yes   |                                 |                              |   | Product Color:  | White                        |   | Glass<br>Tube  |                      | Minimum or                                | der quantity                             | ,                                | Yes         |
| Cannabinoid?  |  | No<br>No  | Country of Origin               | US                           |   |   | TL 001                       |   | Vial Liquid Sgl  |                      |   |  |                                  |             |
| If Unit Dose, is item bar coded to  | unit dose for  | INU   | Country of Origin               | 00                           |   | Product Imprint:  | 12 001                       |   | Vial Liquid Multi  |                      | If Yes how                                | many of whi                              | ch package t                     | tyne?       |
| hospital scanning?  | driit dosc foi                                       |   | Is this product covered u       | under the                    |   |   |                              |   | Vial Powder Sql  |                      |   | Each                                     | m paonago i                      | ., po .     |
| If Unit Dose, indicate NDC here:  |  |   | Trade Agreements Act (          |                              |   |   |                              |   | Vial Power Multi   |                      |   | Inner/Carton                             | /Pack                            |             |
|   |  |   | -                               |                              |   |   |                              |   | Other: Write In  |                      |   | Case                                     |                                  |             |
|   |  |   | FOR GENERIC DRUG PR             | ODUCTS                       |   |   |                              |   |  |                      |   |  |                                  |             |
|   |  |   |                                 |                              |   |   |                              |   |  |                      | 1   |  |                                  |             |
|   |  |   |                                 |                              | Autl  |   | thorized Generic, other      |   | Ph   | ARMACY ORDER         | / BILL UNIT                               |  |                                  |             |
| I. Orange Book Rating:  | AB   |   |                                 |                              |   | section   | on fields are not applicable | Rec. sell unit  | t to ouctomor?   |                      | Dy hilling u                              | nit to pharma                            | acy:                             |             |
| II. Generic Equivalent to What Br   | and?:  |   |                                 |                              |   |   |                              |   | t to customer?   |                      |   |  |                                  |             |
|   |  | Medrol®   |                                 |                              |   |   |                              | 1 b   | oottle of 100 tablets                                      | 1                    | X   | Each                                     |                                  |             |
|   |  |   |                                 |                              |   |   |                              | 1 b<br>(Write-in, e.g   | oottle of 100 tablets                                      |                      |   | Gram                                     |                                  |             |
|   |  |   | Y CHAIN SECURITY ACT (          | DSCSA) INFORMATION           | ION   |   |                              |   | oottle of 100 tablets                                      |                      |   |  |                                  |             |
|   |  | DRUG SUPPL  |                                 |                              |   |   |                              |   | pottle of 100 tablets<br>j. 1 Vial)                        |                      | Х   | Gram<br>Milliliter                       |                                  |             |
| Does supplier meet DSCSA defin  |  | DRUG SUPPL  | Yes                             | (DSCSA) INFORMATI            |   | 0359746000004   |                              |   | pottle of 100 tablets<br>j. 1 Vial)                        | I AND PACKING IN     | Х   | Gram<br>Milliliter                       |                                  |             |
| Is product exempt from DSCSA?   |  | DRUG SUPPL  |                                 | GLN:                         | :   |   |                              |   | pottle of 100 tablets<br>j. 1 Vial)                        |                      | X   | Gram<br>Milliliter                       |                                  |             |
| Is product exempt from DSCSA?  If yes, select exemption:  |  | DRUG SUPPL  | Yes                             |                              | :   | 0359746000004<br>0359746  |                              |   | pottle of 100 tablets<br>j. 1 Vial)                        | Dimensi              | X IFORMATION                              | Gram<br>Milliliter                       | Volume                           | Saleable #  |
| Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in:   |  | DRUG SUPPL  | Yes<br>No                       | GLN:                         | :   | 0359746   |                              | (Write-in, e.g  | oottle of 100 tablets  1 Vial)  ITEM  Weight Lbs.          | Dimension Depth      | X   | Gram<br>Milliliter                       | (Cube)                           | Saleable #  |
| Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in: Is product repackaged?  |  | DRUG SUPPL  | Yes<br>No                       | GLN:                         | :<br>:<br>s, was ori                        | 0359746 ginal product purchased   | 1                            |   | oottle of 100 tablets<br>n. 1 Vial)<br>ITEN                | Dimensi              | X IFORMATION                              | Gram<br>Milliliter                       |                                  |             |
| Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in: Is product repackaged? Is product sold by manufacturer  | s exclusive distrib                                  | DRUG SUPPL'   | Yes<br>No<br>No                 | GLN:                         | :<br>s, was ori                             | 0359746  ginal product purchased  |                              | (Write-in, e.g  | oottle of 100 tablets 1 Vial)  ITEN  Weight Lbs.  0.07     | Dimension Depth      | X<br>IFORMATION<br>Ons (US msm<br>Width   | Gram<br>Milliliter                       | (Cube)<br>9.72                   | Pieces      |
| Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception   | s exclusive distrib<br>on/exemption for p            | DRUG SUPPL'   | Yes<br>No                       | GLN:                         | :<br>s, was ori                             | 0359746 ginal product purchased   |                              | (Write-in, e.g  | oottle of 100 tablets 1 Vial)  ITEN  Weight Lbs.  0.07     | Dimension Depth      | X<br>IFORMATION<br>Ons (US msm<br>Width   | Gram<br>Milliliter                       | (Cube)                           | Pieces      |
| Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in: Is product repackaged? Is product sold by manufacturer  | s exclusive distrib<br>on/exemption for p            | DRUG SUPPL'   | Yes<br>No<br>No                 | GLN:                         | :<br>s, was ori                             | 0359746  ginal product purchased  |                              | (Write-in, e.g  | weight Lbs.  0.07  Sundle/                                 | Dimension Depth 1.8  | X  IFORMATION  Ons (US msm  Width  1.8    | Gram<br>Milliliter                       | 9.72<br>0.00                     | Pieces 1    |
| Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception   | s exclusive distrib<br>on/exemption for p            | DRUG SUPPL' rer?  utor? roduct?                                 | Yes<br>No<br>No                 | GLN: GCP: If yes direc Provi | :<br>s, was ori                             | 0359746  ginal product purchased  |                              | Item/Each: Box/Carton/EInner Pack:  | oottle of 100 tablets 1 Vial)  ITEN  Weight Lbs.  0.07     | Dimension Depth      | X<br>IFORMATION<br>Ons (US msm<br>Width   | Gram<br>Milliliter                       | (Cube)<br>9.72                   | Pieces      |
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| Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer Has FDA granted waiver/exceptic If yes, attach documentation fro  | s exclusive distrib<br>on/exemption for p<br>om FDA. | DRUG SUPPL' rer?  utor? roduct?  GTIN                           | Yes<br>No<br>No<br>No           | GLN: GCP: If yes direc Provi | :<br>s, was ori<br>ct from mf<br>ride sourc | 0359746 ginal product purchased r? e manufacturer for repa                              |                              | Item/Each: Box/Carton/Einner Pack: Case:  | weight Lbs.  0.07  Sundle/                                 | Dimension Depth 1.8  | X  IFORMATION  Ons (US msm  Width  1.8    | Gram<br>Milliliter                       | 9.72<br>0.00                     | Pieces 1    |
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL H  | AZARD 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  |   |  |  |  |  |  |
|   |   |  |  |  |  |  |



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

#### Version 2021

#### 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?  |