



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  New Product  Post Launch Change Final VersionDate: 

| PRODUCT INFORMATION   |  |
|---|--|
| Company Name:   | Jubilant Cadista Pharmaceuticals Inc.  |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 201506   |
| DUNS:   | 022490515  |
| Proprietary Name (If Applicable) and Established Name:              | Valacyclovir Tablet  |
| Selling Unit NDC:   | 59746-0324-30  |
| Individual Unit NDC:  |  |
| UPC:  | 3-59746-324-30-8   |
| CVX Code:   |  |
| MXV Code:   |  |
| Description:  | Valacyclovir Tablet 500mg 30ct   |
| Active Ingredient(s):   | Valacyclovir   |
| URL for Additional Product Information:                             | www.cadista.com  |
| Address:  | 207 Kiley Drive<br>Salisbury<br>Key Contact: Jackie Emershaw<br>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   |
|   | 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:                           | 30ct           |
| Strength:                       | 500mg          |
| Dosage Form:                    | TAB            |
| Product Shape:                  | capsule shaped |
| Product Color:                  | Blue           |
| Product Imprint:                | "C324" "500"   |

| ORDER INFORMATION                          |   |
|--|---|
| Unit of Sale                               | What is the NDC selling unit?           |
| <input checked="" type="checkbox"/> Bottle | 1 Case of 48 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 | 48 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?:      | Valtrex   |
| <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)     | <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            |
| GLN:   | 8902805000006 |
| 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             |           |
| Case:                            | 7.35        | 15.25                  | 5.5    | 11.75 | 985.53125     | 48        |
| Pallet:                          |             |                        |        |       | 0             |           |
| UPC:                             | Case:       |                        |        |       |               |           |
|                                  | Carton:     |                        |        |       |               |           |

| GTIN PRODUCT INFORMATION |       |               |      |          |                |  |
|--------------------------|-------|---------------|------|----------|----------------|--|
| Serialized?              | Level | Saleable Unit |      | Quantity | GTIN-14        |  |
|                          |       | Item          | Unit |          |                |  |
| If not, when?            |       |               |      | 1        | 00359746324308 |  |
| Items aggregated?        |       |               |      | 48       | 40359746324306 |  |
|                          |       |               |      |          |                |  |
|                          |       |               |      |          |                |  |
|                          |       |               |      |          |                |  |
|                          |       |               |      |          |                |  |
|                          |       |               |      |          |                |  |
|                          |       |               |      |          |                |  |

| COST INFORMATION                    |         | WHOLESALE USE ONLY: |  |
|-------------------------------------|---------|---------------------|--|
| Regular Cost                        |         | Vendor #:           |  |
| Invoice Cost (WAC) (\$)             | \$17.22 | 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)?

ARCOS Reportable?

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

|   |   |
|---|---|
| <input type="checkbox"/> Organic  | <input type="checkbox"/> Corrosive      |
| <input type="checkbox"/> Inorganic  | <input type="checkbox"/> Oxidizer       |
| <input type="checkbox"/> Steroid/Androgen   | <input type="checkbox"/> Contact Hazard |
| <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100px;" type="text"/> |   |
| Is the product a NIOSH hazardous drug? <input style="width: 100px;" type="text"/>                               |   |
| If yes, indicate which: <input style="width: 300px;" type="text"/>  |   |

### 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:<br>a. EDI <input type="checkbox"/> Yes<br>b. Autofax <input type="checkbox"/> Yes Fax Number: <input type="text"/><br>c. Fax <input type="checkbox"/> Yes Fax Number: <input type="text"/><br>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/><br>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/><br>Minimum Order Quantity: <input type="text" value="48"/><br>Supplier's Customer Service Number: <input type="text" value="(410) 912-3722"/><br>Contracted 3PL company / contact #:<br>Name: <input type="text"/><br>Phone: <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>PO Receipt cut off time: <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: 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"/>   | <b>Return Instructions</b><br>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?<br><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"/>   |   |
| Miscellaneous Notes:  | ADDITIONAL INFORMATION  |
| <input type="text"/>  | Is product order for scheduled patient procedure? <input type="checkbox"/><br>Is product order for restocking purposes? <input type="checkbox"/>  |