



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

Version 2024 Introduction Type: Final Version Date:

| PRODUCT INFORMATION | |
|--|--|
| Company Name: | Jubilant Cadista Pharmaceuticals Inc. |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 208236 |
| Application: | ANDA |
| Medical Device Class, if applicable: | |
| DUNS: | 118694141 |
| Proprietary Name (If Applicable) and Established Name: | Roflumilast |
| Selling Unit NDC: | 59746-0802-30 |
| Unit of Use NDC: | |
| CVX Code: | |
| UPC: | 3-59746-802-30-1 |
| MX Code: | |
| Description: | Roflumilast Tab 0.50mg 30ct |
| Active Ingredient(s): | Roflumilast |
| 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: | Selective phosphodiesterase-4 inhibitors |
| Address 2: | Suite 325 |
| State: | PA |
| Zip: | 19067 |
| Email: | customer.service@cadista.com |
| Fax: | N/A |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS* | |
|--|--|
| 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="text" value="No"/> |
| Is this product to be shipped to customers on dry ice? | <input type="text" value="No"/> |
| 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? | |
| Special returns requirements for this product? | <input type="text" value="No"/> |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | <input type="text" value="No"/> |
| e. Shelf life: | |
| Initial shelf life at launch (if different): | <input type="text" value="24"/> Months |

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|---|---|---|---|
| The product is? | | Is the Product... Is the Product... Orphan Drug Status | <input type="text" value="Neither"/> |
| a legend device? | <input type="text" value="No"/> | Direct-Ship Only | <input type="text" value=""/> |
| if yes, enter class # | | | |
| a product kit? | <input type="text" value="No"/> | | |
| if yes, list NDCs of component parts | | FDA Approval Status | |
| reverse numbered? | <input type="text" value="No"/> | | |
| co-licensed? | <input type="text" value="No"/> | Allergens Present | |
| latex-free? | <input type="text" value="Yes"/> | | |
| preservative-free? | <input type="text" value="No"/> | Country of Origin | <input type="text" value="USA"/> |
| correctional institution block? | <input type="text" value="Yes"/> | | |
| opioid? | <input type="text" value="No"/> | | |
| Cannabinoid? | <input type="text" value="No"/> | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text" value=""/> | Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="Yes"/> |
| If Unit Dose, indicate NDC here: | | | |
| Size: | <input type="text" value="30ct"/> | Strength: | <input type="text" value="0.50mg"/> |
| Dosage Form: | <input type="text" value="TABLET"/> | Product Shape: | <input type="text" value="round, beveled-edges"/> |
| Product Color: | <input type="text" value="White- to- off white"/> | Product Imprint: | <input type="text" value="*A 117*"/> |

| ORDER INFORMATION | |
|--|---|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 bottle of 30 tablets"/> |
| <input type="checkbox"/> Box/ Carton | <input type="text" value="(Write-in, e.g. 1 Box of 10 Vials)"/> |
| <input type="checkbox"/> Ampule | |
| <input type="checkbox"/> Glass | Minimum order quantity? <input type="text" value="Yes"/> |
| <input type="checkbox"/> Tube | |
| <input type="checkbox"/> Vial Liquid Sgl | |
| <input type="checkbox"/> Vial Liquid Multi | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Powder Sgl | <input type="text" value="24"/> Each |
| <input type="checkbox"/> Vial Power Multi | <input type="text" value=""/> |
| <input type="checkbox"/> Other: Write In | <input type="text" value=""/> |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | <input type="text" value="AB"/> |
| II. Generic Equivalent to What Brand?: | <input type="text" value="Daliresp®"/> |
| <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: |
| <input type="text" value="1 bottle of 30 tablets"/> | <input checked="" type="checkbox"/> Each |
| (Write-in, e.g. 1 Vial) | <input type="checkbox"/> Gram |
| HCPCS J-Code: | <input type="checkbox"/> Milliliter |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|--|
| Does supplier meet DSCSA definition of manufacturer? | <input type="text" value="Yes"/> |
| Is product exempt from DSCSA? | <input type="text" value="No"/> |
| If yes, select exemption: | |
| Other exemption - Write in: | |
| Is product repackaged? | <input type="text" value="No"/> |
| Is product sold by manufacturer's exclusive distributor? | <input type="text" value="No"/> |
| Has FDA granted waiver/exception/exemption for product? | <input type="text" value="No"/> |
| If yes, attach documentation from FDA. | |
| GLN: | <input type="text" value="0359746000004"/> |
| GCP: | <input type="text" value="0359746"/> |
| If yes, was original product purchased direct from mfr? | <input type="text" value=""/> |
| 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: | 0.075 | 1.9 | 1.9 | 4 | 14.44 | 1 |
| Case: | 2.46 | 15.5 | 11.75 | 5.25 | 956.16 | 24 |
| Pallet: | | | | | 0 | |

| GTIN AND HIBCC PRODUCT INFORMATION | | | | |
|---|---------------|-------------------|-------|----------------|
| Saleable Unit of Measure | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14 |
| <input checked="" type="checkbox"/> Item/Each | N | 1 | | 00359746802301 |
| <input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack | N | 24 | | 40359746802309 |
| <input type="checkbox"/> Case | | | | |
| <input type="checkbox"/> Pallet | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------|--|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | <input type="text" value="\$340.55"/> | Whsl. Code #: | |
| As of date: | <input type="text" value="6/26/2026"/> | Fineline Code: | |



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

Version 2024

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
- 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 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:



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

Version 2024

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