



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

Version 2021

Introduction Type: Post Launch Change

Final Version

Date: 7/12/2021

| PRODUCT INFORMATION | | | | SPECIAL HANDLING AND STORAGE REQUIREMENTS* | | | |
|---|-------------|--|--------|--|---------------|---|--|
| Company Name: <input type="text" value="Jubilant Cadista Pharmaceuticals Inc."/> | | Application: <input type="text" value="ANDA"/> | | a. Temperature – Indicate the USP temperature range for this product. | | | |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="079132"/> | | | | Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> | | | |
| Medical Device Class, if applicable: <input type="text"/> | | | | Other Temperature Range Requirement (write in) <input type="text"/> | | | |
| DUNS: <input type="text" value="022490515"/> | | | | Notes <input type="text"/> | | | |
| Proprietary Name (If Applicable) and Established Name: <input type="text" value="Lamotrigine Tablets"/> | | Unit of Use NDC: <input type="text"/> | | Is this product to be shipped to customers on ice? <input type="checkbox"/> No | | | |
| Selling Unit NDC: <input type="text" value="59746-245-01"/> | | UPC: <input type="text" value="3-59746-245-01-6"/> | | Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No | | | |
| UDI <input type="text"/> | | CVX Code: <input type="text"/> | | MVX Code: <input type="text"/> | | | |
| Description: <input type="text" value="Lamotrigine 25mg 100ct Tablet"/> | | | | b. Contact for temperature excursion questions: | | | |
| Active Ingredient(s): <input type="text" value="Lamotrigine"/> | | | | Name: <input type="text" value="Customer Service"/> | | | |
| URL for Additional Product Information: <input type="text" value="www.cadista.com/products/full-product-list"/> | | | | Number: <input type="text" value="(800) 313-4623"/> | | | |
| Address: <input type="text" value="207 Kiley Drive"/> | | Address 2: <input type="text"/> | | Group E-mail: <input type="text" value="customer.service@cadista.com"/> | | | |
| City: <input type="text" value="Salisbury"/> | | State: <input type="text" value="MD"/> | | Zip: <input type="text" value="21801"/> | | | |
| Key Contact: <input type="text" value="Jackie Emershaw"/> | | Email: <input type="text" value="Jackie.Emershaw@jubl.com"/> | | c. Special regulations for product in any states? | | | |
| Phone Number: <input type="text" value="(410) 912-3722"/> | | Fax: <input type="text" value="(215) - 443 - 9646"/> | | Special returns requirements for this product? <input type="checkbox"/> No | | | |
| Product Therapeutic Classification: <input type="text" value="Antiepileptic"/> | | | | Protect product (unit of sale) from light? <input type="checkbox"/> No | | | |
| ADDITIONAL PRODUCT INFORMATION | | | | PRODUCT DESCRIPTION INFORMATION | | | |
| The product is? a legend device? <input type="checkbox"/> No | | Is the Product... Direct-Ship Only <input type="checkbox"/> | | Size: <input type="text" value="100 count"/> | | | |
| if yes, enter class # <input type="text"/> | | Is the Product... Neither <input type="checkbox"/> | | Strength: <input type="text" value="25mg"/> | | | |
| a product kit? <input type="checkbox"/> No | | Orphan Drug Status <input type="text"/> | | Dosage Form: <input type="text" value="TABLET"/> | | | |
| if yes, list NDCs of component parts <input type="text"/> | | FDA Approval Status <input type="text"/> | | Product Shape: <input type="text" value="Round"/> | | | |
| reverse numbered? <input type="checkbox"/> No | | Allergens Present <input type="text"/> | | Product Color: <input type="text" value="White"/> | | | |
| co-licensed? <input type="checkbox"/> No | | Country of Origin <input type="text" value="US"/> | | Product Imprint: <input type="text" value="J 245"/> | | | |
| latex-free? <input type="checkbox"/> Yes | | Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes | | | | | |
| preservative-free? <input type="checkbox"/> No | | | | | | | |
| correctional institution block? <input type="checkbox"/> Yes | | | | | | | |
| opioid? <input type="checkbox"/> No | | | | | | | |
| Cannabinoid? <input type="checkbox"/> No | | | | | | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> | | | | | | | |
| If Unit Dose, indicate NDC here: <input type="text"/> | | | | | | | |
| FOR GENERIC DRUG PRODUCTS | | | | | | | |
| I. Orange Book Rating: <input type="text" value="AB"/> | | <input type="checkbox"/> Authorized Generic | | *If Authorized Generic, other section fields are not applicable | | | |
| II. Generic Equivalent to What Brand?: <input type="text" value="Lamictal"/> | | | | | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | | | | | | | |
| Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes | | GLN: <input type="text" value="0359746000004"/> | | | | | |
| Is product exempt from DSCSA? <input type="checkbox"/> No | | GCP: <input type="text" value="0359746"/> | | | | | |
| If yes, select exemption: <input type="text"/> | | If yes, was original product purchased direct from mfr? <input type="checkbox"/> | | | | | |
| Other exemption - Write in: <input type="text"/> | | Provide source manufacturer for repackaged product <input type="text"/> | | | | | |
| Is product repackaged? <input type="checkbox"/> No | | | | | | | |
| Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No | | | | | | | |
| Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No | | | | | | | |
| If yes, attach documentation from FDA. <input type="text"/> | | | | | | | |
| GTIN AND HIBCC PRODUCT INFORMATION | | | | | | | |
| Saleable Unit of Measure | | Saleable Quantity | | HIBCC | | GTIN-14 | |
| <input checked="" type="checkbox"/> Item/Each | | <input type="text" value="1"/> | | <input type="text"/> | | <input type="text" value="00359746245016"/> | |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack | | <input type="text"/> | | <input type="text"/> | | <input type="text"/> | |
| <input checked="" type="checkbox"/> Case | | <input type="text" value="48"/> | | <input type="text"/> | | <input type="text" value="40359746245014"/> | |
| <input type="checkbox"/> Pallet | | <input type="text"/> | | <input type="text"/> | | <input type="text"/> | |
| <input type="text"/> | | <input type="text"/> | | <input type="text"/> | | <input type="text"/> | |
| <input type="text"/> | | <input type="text"/> | | <input type="text"/> | | <input type="text"/> | |
| <input type="text"/> | | <input type="text"/> | | <input type="text"/> | | <input type="text"/> | |
| <input type="text"/> | | <input type="text"/> | | <input type="text"/> | | <input type="text"/> | |
| <input type="text"/> | | <input type="text"/> | | <input type="text"/> | | <input type="text"/> | |
| ORDER INFORMATION | | | | PHARMACY ORDER / BILL UNIT | | | |
| Unit of Sale | | What is the NDC selling unit? | | Rec. sell unit to customer? | | | |
| <input checked="" type="checkbox"/> Bottle | | <input type="text" value="1 bottles of 100 tablets"/> | | <input type="text" value="1 bottles of 100 tablets"/> | | | |
| <input type="checkbox"/> Box/Carton | | (Write-in, e.g. 1 Box of 10 Vials) | | Rx billing unit to pharmacy: | | | |
| <input type="checkbox"/> Ampule | | | | <input checked="" type="checkbox"/> Each | | | |
| <input type="checkbox"/> Glass | | | | <input type="checkbox"/> Gram | | | |
| <input type="checkbox"/> Tube | | | | <input type="checkbox"/> Milliliter | | | |
| <input type="checkbox"/> Vial Liquid Sgl | | | | Minimum order quantity? <input type="checkbox"/> Yes | | | |
| <input type="checkbox"/> Vial Liquid Multi | | | | If Yes, how many of which package type? | | | |
| <input type="checkbox"/> Vial Powder Sgl | | | | <input type="text" value="48"/> Each | | | |
| <input type="checkbox"/> Vial Power Multi | | | | <input type="text"/> | | | |
| <input type="checkbox"/> Other: Write In | | | | <input type="text"/> | | | |
| <input type="text"/> | | | | <input type="text"/> | | | |
| <input type="text"/> | | | | <input type="text"/> | | | |
| ITEM AND PACKING INFORMATION | | | | | | | |
| | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | Saleable # Pieces | |
| | Depth | Width | Height | | | | |
| Item/Each: | 0.69 | 1.9 | 1.9 | 4 | 14.44 | 1 | |
| Box/Carton/Bundle/Inner Pack: | | | | | 0.00 | | |
| Case: | 6.4 | 16.25 | 12 | 4.5 | 877.50 | 48 | |
| Pallet: | | | | | 0.00 | | |
| COST INFORMATION | | | | WHOLESALE USE ONLY: | | | |
| Regular Cost | | | | Vendor #: | | <input type="text"/> | |
| Invoice Cost (WAC) (\$) | | <input type="text" value="\$4.47"/> | | Whsl. Code #: | | <input type="text"/> | |
| As of date: | | <input type="text"/> | | Fineline Code: | | <input type="text"/> | |

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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

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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

SDS Hazard Classification

- Organic Corrosive
- Inorganic Oxidizer
- Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, identify No

NFPA Storage Level:

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?



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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"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></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>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <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: 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> |