



# 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"/>                               |   | <b>a. Temperature – Indicate the USP temperature range for this product.</b>                        |               |                   |  |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="090768"/>         |   |  |   | 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="Donepezil HCl Tablets"/>       |   | Unit of Use NDC: <input type="text" value="3-59746-330-90-3"/>               |   | Is this product to be shipped to customers on ice? <input type="text" value="No"/>                  |               |                   |  |
| Selling Unit NDC: <input type="text" value="59746-330-90"/>   |   | CVX Code: <input type="text"/>   |   | Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>              |               |                   |  |
| UDI: <input type="text"/>   |   | MVX Code: <input type="text"/>   |   |   |               |                   |  |
| Description: <input type="text" value="Donepezil Hydrochloride 10mg 90ct Tablet"/>                              |   |  |   | <b>b. Contact for temperature excursion questions:</b>  |               |                   |  |
| Active Ingredient(s): <input type="text" value="Donepezil Hydrochloride"/>                                      |   |  |   | 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"/>                                       |   |   |               |                   |  |
| Key Contact: <input type="text" value="Jackie Emershaw"/>   |   | Zip: <input type="text" value="21801"/>                                      |   |   |               |                   |  |
| Phone Number: <input type="text" value="(410) 912-3722"/>   |   | Email: <input type="text" value="Jackie.Emershaw@jubl.com"/>                 |   |   |               |                   |  |
| Product Therapeutic Classification: <input type="text" value="Dementia Treatment"/>                             |   | Fax: <input type="text" value="(215) - 443 - 9646"/>                         |   |   |               |                   |  |
| ADDITIONAL PRODUCT INFORMATION  |   |  | PRODUCT DESCRIPTION INFORMATION             |   |               |                   |  |
| The product is? a legend device? <input type="text" value="No"/>  | Is the Product... Direct-Ship Only <input type="text"/>                                       | Size: <input type="text" value="90 count"/>                                  |   |   |               |                   |  |
| if yes, enter class # a product kit? <input type="text"/>   | Is the Product... Neither <input type="text"/>  | Strength: <input type="text" value="10mg"/>                                  |   |   |               |                   |  |
| if yes, list NDCs of component parts reverse numbered? <input type="text"/>                                     | Orphan Drug Status <input type="text"/>   | Dosage Form: <input type="text" value="TABLETS"/>                            |   |   |               |                   |  |
| co-licensed? <input type="text" value="No"/>  | FDA Approval Status <input type="text"/>  | Product Shape: <input type="text" value="Round"/>                            |   |   |               |                   |  |
| latex-free? <input type="text" value="Yes"/>  | Allergens Present <input type="text"/>  | Product Color: <input type="text" value="White"/>                            |   |   |               |                   |  |
| preservative-free? <input type="text" value="No"/>  | Country of Origin <input type="text" value="IN"/>   | Product Imprint: <input type="text" value="J / 10"/>                         |   |   |               |                   |  |
| correctional institution block? opioid? <input type="text" value="Yes"/>  | Is this product covered under the Trade Agreements Act (TAA)? <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"/>                        |   |  |   |   |               |                   |  |
| 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="Aricept"/>                                     |   |  |   |   |               |                   |  |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  |   |  |   |   |               |                   |  |
| Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>                           |   | GLN: <input type="text" value="8902805000006"/>                              |   |   |               |                   |  |
| Is product exempt from DSCSA? <input type="text" value="No"/>   |   | GCP: <input type="text" value="0359746"/>                                    |   |   |               |                   |  |
| If yes, select exemption: Other exemption - Write in: <input type="text"/>                                      |   | If yes, was original product purchased direct from mfr? <input type="text"/> |   |   |               |                   |  |
| Is product repackaged? <input type="text" value="No"/>  |   | Provide source manufacturer for repackaged product <input type="text"/>      |   |   |               |                   |  |
| 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. <input type="text"/>   |   |  |   |   |               |                   |  |
| GTIN AND HIBCC PRODUCT INFORMATION  |   |  |   |   |               |                   |  |
| Saleable Unit of Measure  | Saleable Quantity   | HIBCC  | GTIN-14                                     | Unit of Use GTIN-14   |               |                   |  |
| <input checked="" type="checkbox"/> Item/Each   | <input type="text" value="1"/>  | <input type="text"/>   | <input type="text" value="00359746330903"/> | <input type="text"/>  |               |                   |  |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack   | <input type="text"/>  | <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="40359746330901"/> | <input type="text"/>  |               |                   |  |
| <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"/>  |               |                   |  |
| ORDER INFORMATION   |   |  | PHARMACY ORDER / BILL UNIT                  |   |               |                   |  |
| Unit of Sale  |   | What is the NDC selling unit?  |   |   |               |                   |  |
| <input checked="" type="checkbox"/> Bottle  | <input type="text"/>  | 1 bottle of 90 tablets   |   |   |               |                   |  |
| <input type="checkbox"/> Box/Carton   | <input type="text"/>  | (Write-in, e.g. 1 Box of 10 Vials)   |   |   |               |                   |  |
| <input type="checkbox"/> Ampule   | <input type="text"/>  |  |   |   |               |                   |  |
| <input type="checkbox"/> Glass  | <input type="text"/>  | Minimum order quantity? <input type="text" value="Yes"/>                     |   |   |               |                   |  |
| <input type="checkbox"/> Tube   | <input type="text"/>  |  |   |   |               |                   |  |
| <input type="checkbox"/> Vial Liquid Sgl  | <input type="text"/>  |  |   |   |               |                   |  |
| <input type="checkbox"/> Vial Liquid Multi  | <input type="text"/>  | 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"/>  | Inner/Carton/Pack  |   |   |               |                   |  |
| <input type="checkbox"/> Other: Write In  | <input type="text"/>  | Case   |   |   |               |                   |  |
| ITEM AND PACKING INFORMATION  |   |  |   |   |               |                   |  |
|   | Weight Lbs.   | Dimensions (US msmts.)   |   |   | Volume (Cube) | Saleable # Pieces |  |
|   |   | Depth  | Width                                       | Height  |               |                   |  |
| Item/Each:  | 0.1   | 1.9  | 1.9   | 4   | 14.44         | 1                 |  |
| Box/Carton/Bundle/Inner Pack:   |   |  |   |   | 0.00          |                   |  |
| Case:   | 7.7   | 14.75  | 11.13                                       | 5   | 820.84        | 48                |  |
| Pallet:   |   |  |   |   | 0.00          |                   |  |
| COST INFORMATION  |   |  | WHOLESALE USE ONLY:                         |   |               |                   |  |
| Regular Cost  |   |  | Vendor #:                                   |   |               |                   |  |
| Invoice Cost (WAC) (\$)   |   | \$5.60   | Whsl. Code #:                               |   |               |                   |  |
| As of date:   |   |  | Fineline Code:                              |   |               |                   |  |

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?  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?  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?  No

Is this product regulated for shipment by 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?  No

Is the product restricted for air shipment? If so, indicate restriction:  No

- 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  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?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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><b>Purchase order daily receipt cut off time by supplier</b></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><b>Overnight receipt available:</b> <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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <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>  |