



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

Version 2021

Introduction Type: Post Launch Change

Final Version

Date: 6/17/2024

PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. **Application:** ANDA

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 077563

Medical Device Class, if applicable:

DUNS: 022490515

Proprietary Name (If Applicable) and Established Name: Cyclobenzaprine HCl Tablets

Selling Unit NDC: 59746-211-10 **Unit of Use NDC:** **UPC:** 3-59746-211-10-3

UDI **CVX Code:** **MXV Code:**

Description: Cyclobenzaprine Hydrochloride 5mg 1000ct Tablet

Active Ingredient(s): Cyclobenzaprine Hydrochloride

URL for Additional Product Information: www.cadista.com/products/full-product-list

Address: 790 Township Line Road **Address 2:** Suite 325

City: Yardley **State:** PA **Zip:** 19067

Key Contact: Customer Service **Email:** customer.service@cadista.com

Phone Number: (800) 313-4623 **Fax:** N/A

Product Therapeutic Classification: Analgesic Muscle Relaxant

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range:

Other Temperature Range Requirement (write in):

Notes:

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 Service

Number: (800) 313-4623

Group E-mail: customer.service@cadista.com

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: Months

Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

The product is a legend device? No

If yes, enter class # a product kit? No

If yes, list NDCs of component parts reverse numbered? No

co-licensed? No

latex-free? Yes

preservative-free? No

correctional institution block? Yes

opioid? No

Cannabinoid? No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

Is the Product... Direct-Ship Only Neither

Is the Product... Orphan Drug Status

FDA Approval Status

Allergens Present

Country of Origin

Is this product covered under the Trade Agreements Act (TAA)? Yes No

PRODUCT DESCRIPTION INFORMATION

Size: 1000 count

Strength: 5mg

Dosage Form: TABLETS

Product Shape: Round

Product Color: Orange

Product Imprint: TL 211

ORDER INFORMATION

Unit of Sale

<input checked="" type="checkbox"/>	Bottle
<input type="checkbox"/>	Box/Carton
<input type="checkbox"/>	Ampule
<input type="checkbox"/>	Glass
<input type="checkbox"/>	Tube
<input type="checkbox"/>	Vial Liquid Sgl
<input type="checkbox"/>	Vial Liquid Multi
<input type="checkbox"/>	Vial Powder Sgl
<input type="checkbox"/>	Vial Power Multi
<input type="checkbox"/>	Other: Write In

What is the NDC selling unit?
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

<input type="text" value="12"/>	Each
<input type="text"/>	Inner/Carton/Pack
<input type="text"/>	Case

FOR GENERIC DRUG PRODUCTS

Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:

II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

<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 No

Is product exempt from DSCSA?

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

If yes, attach documentation from FDA.

GLN: 0359746000004

GCP: 0359746

If yes, was original product purchased direct from mfr?

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:	0.4	2.4	2.4	4.75	27.36	1
Case:	5.16	10.25	7.5	5.13	394.37	12
Pallet:					0.00	

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	1		00359746211103	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	12		40359746211101	
<input type="checkbox"/> Pallet				

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

*Please provide any additional information on page 2.

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

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
- 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 by State(s)? No Yes
- ARCOS Reportable? No Yes
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II) No Yes
- If yes, indicate which:
- 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:



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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
Purchase orders may be accepted by: a. EDI <input style="width: 50px;" type="text"/> b. Autofax <input style="width: 50px;" type="text"/> Fax Number: <input style="width: 100px;" type="text"/> c. Fax <input style="width: 50px;" type="text"/> Fax Number: <input style="width: 100px;" type="text"/> d. Phone only <input style="width: 50px;" type="text"/> Phone No.: <input style="width: 100px;" type="text"/> e. Supplier Web Site only <input style="width: 50px;" type="text"/> Site Address: <input style="width: 100px;" type="text"/> Minimum Order Quantity: <input style="width: 150px;" type="text"/> Supplier's Customer Service Number: <input style="width: 150px;" type="text"/> Contracted 3PL company / contact #: Name: <input style="width: 150px;" type="text"/> Phone: <input style="width: 150px;" type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input style="width: 150px;" type="text"/> Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days Ships same day for next day receipt: <input style="width: 50px;" type="text"/> Ships for second day receipt: <input style="width: 50px;" type="text"/> Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input style="width: 50px;" type="text"/> Drop Ship service fee billed with each order: <input style="width: 50px;" type="text"/> Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text"/> Comments: <input style="width: 150px; height: 40px;" type="text"/>	Overnight receipt available: <input style="width: 50px;" type="text"/> PO Receipt cut off time: <input style="width: 150px;" type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input style="width: 50px;" type="text"/> PO Receipt Cut off time: <input style="width: 150px;" type="text"/> Saturday Overnight receipt available: <input style="width: 50px;" type="text"/> PO Receipt Cut off time: <input style="width: 150px;" type="text"/> Order receipt method: Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 50px;" type="text"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 50px;" type="text"/> EDI: <input style="width: 50px;" type="text"/> Overnight Fees apply: <input style="width: 50px;" type="text"/> Other fees apply: <input style="width: 50px;" type="text"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50px;" type="text"/> Restricted to retail pharmacy only: <input style="width: 50px;" type="text"/> Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text"/> Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text"/> Comments: <input style="width: 150px; height: 40px;" type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input style="width: 100px;" type="text"/> Physician Name: <input style="width: 150px;" type="text"/> Physician/Clinic Phone #: <input style="width: 150px;" type="text"/> Physician State License #: <input style="width: 150px;" type="text"/> Physician/Clinic DEA #: <input style="width: 150px;" type="text"/> Physician/Clinic Specialty: <input style="width: 150px;" type="text"/>	Contact # if product is received damaged: <input style="width: 100px;" type="text"/> Is product returnable for credit: <input style="width: 50px;" type="text"/> URL/Link to returns policy: <input style="width: 150px;" type="text"/> Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/> If so, which states? Other requirements? Comments? <input style="width: 150px; height: 40px;" type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input style="width: 150px; height: 80px;" type="text"/>	Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/> Is product order for restocking purposes? <input style="width: 50px;" type="text"/>