

Version 2021

Introduction Type: Post Launch Change Final Version

Date: 6/9/2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
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: 59746-177-10 Unit of Use NDC: UPC: 3-59746-177-10-2 UDI: CVX Code: MXV Code: Description: Cyclobenzaprine Hydrochloride 10mg 1000ct Tablet Active Ingredient(s): Cyclobenzaprine Hydrochloride URL for Additional Product Information: www.cadista.com/products/full-product-list Address: 207 Kiley Drive Address 2: City: Salisbury State: MD Zip: 21801 Key Contact: Customer Service Email: customer.service@cadista.com Phone Number: (800) 313-4623 Fax: N/A Product Therapeutic Classification: Analgesic Muscle Relaxant				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): <input type="text"/> Notes: <input type="text"/> Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> 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? <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No d. Store product (unit of sale) upright? <input type="checkbox"/> No Protect product (unit of sale) from light? <input type="checkbox"/> No e. Shelf life: Initial shelf life at launch (if different): <input type="text" value="24"/> Months Months									
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION									
The product is a legend device? <input type="checkbox"/> No if yes, enter class # a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No latex-free? <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"/>		Is the Product... Direct-Ship Only <input type="checkbox"/> Neither <input type="checkbox"/> Is the Product... Orphan Drug Status <input type="checkbox"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text"/> Country of Origin US <input type="text"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes		Size: 1000 count Strength: 10mg Dosage Form: TABLETS Product Shape: Round Product Color: Yellow Product Imprint: TL 177		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? <input type="text" value="1 bottle of 1000 tablets"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> 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													
I. Orange Book Rating: AB <input type="checkbox"/> Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: Flexeril®													
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION													
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes <input type="checkbox"/> No Is product exempt from DSCSA? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, select exemption: Other exemption - Write in: <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.				GLN: 0359746000004 GCP: 0359746 If yes, was original product purchased direct from mfr? <input type="checkbox"/> Provide source manufacturer for repackaged product <input type="text"/>									
GTIN AND HIBCC PRODUCT INFORMATION													
Saleable Unit of Measure <input checked="" type="checkbox"/> Item/Each <input type="checkbox"/> Box/Carton/Bundle/Inner Pack <input checked="" type="checkbox"/> Case <input type="checkbox"/> Pallet		Saleable Quantity <input type="text" value="1"/> <input type="text" value="12"/>		HIBCC <input type="text"/> <input type="text"/>		GTIN-14 <input type="text" value="00359746177102"/> <input type="text" value="40359746177100"/>		Unit of Use GTIN-14 <input type="text"/>					
COST INFORMATION				WHOLESALE USE ONLY:									
Regular Cost <input type="text"/> Invoice Cost (WAC) (\$) <input type="text" value="\$67.46"/> As of date: <input type="text"/>				Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/>									
ITEM AND PACKING INFORMATION													
		Weight Lbs.		Dimensions (US msmts.)		Volume (Cube)	Saleable # Pieces						
		Depth		Width		Height							
Item/Each:		0.4		2.4		2.4	5.08						
Box/Carton/Bundle/Inner Pack:							29.26						
Case:		5.26		10.25		7.75	5.13						
Pallet:							407.51						
							12						
						0.00							
						0.00							

*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:



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

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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 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)

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