



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Product Post Launch Change Final Version

Date: 10/15/19

PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A77563
 DUNS: 022490515
 Proprietary Name (If Applicable) and Established Name: Cyclobenzaprine HCL Tablets
 Selling Unit NDC: 59746-0177-10 Individual Unit NDC: _____ UPC: 3-59746-177-10-2
 UDI: _____ CVX Code: _____ MVX Code: _____
 Description: Cyclobenzaprine HCL 10mg Tablets 1000ct
 Active Ingredient(s): Cyclobenzaprine
 URL for Additional Product Information: www.cadista.com
 Address: 207 Kiley Drive Salisbury, MD 21801
 Key Contact: Jackie Emershaw Email: Jackie.Emershaw@cadista.com
 Phone Number: (410) 912-3722 Fax: (215) 443-9646
 Product Therapeutic Classification: _____

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77°)
 Other Temperature Range Requirement (write in): _____
 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 Support
 Number: (800) 313-4623
 Group E-mail: _____
 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: 24 Months
 Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION**PRODUCT DESCRIPTION INFORMATION**

Is the Product...
 a legend device? Yes
 reverse numbered? No
 co-licensed? No
 Is the Product... Direct-Ship Only
 Is the Product... _____
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose NDC, indicate NDC here: _____
 Country of Origin: _____
 Is this product covered under the Trade Agreements Act (TAA)?

Size: 1000ct
 Strength: 10mg
 Dosage Form: TAB
 Product Shape: Round
 Product Color: Yellow
 Product Imprint: debossed TL-177

ORDER INFORMATION

Unit of Sale: Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Powder Multi
 Other: Write In _____
 What is the NDC selling unit?
 1 case of 12 bottles
 (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity? Yes
 If Yes, how many of which package type?
 12 Each
 Inner/ Carton/Pack
 Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Flexeril®

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? _____
 (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No
 Is product exempt from DSCSA? Yes No
 If yes, select exemption: _____
 Other exemption - Write in: _____
 Is product repackaged? Yes No
 Is product sold by manufacturer's exclusive distributor? Yes No
 Has FDA granted waiver/exception/exemption for product? Yes No
 GLN: 359746000004
 If Yes, was original product purchased direct from mfr? Yes No
 If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.36	2	4	2	16	1
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	21	20.25	14.75	5.25	1568.11	12
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized?	If not, when?	Items aggregated?	Level	Saleable Unit		Quantity	GTIN-14
				<input checked="" type="checkbox"/>	<input type="checkbox"/>		
<input checked="" type="checkbox"/>			Item	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1	00359746177102
			Box/ Carton/ Bundle/ Inner Pack	<input type="checkbox"/>	<input type="checkbox"/>		
			Case	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12	40359746177100
			Pallet	<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>	<input type="checkbox"/>		

COST INFORMATION**WHOLESALE USE ONLY:**

Regular Cost: _____
 Invoice Cost (WAC) (\$): \$67.46
 Federal Excise Tax Per Unit of Sale: _____
 As of date: _____
 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: _____

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 or 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?

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

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:

Is it a scheduled listed chemical product?

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No
 If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:
 Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

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 Information (Page 3)

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 b. Autofax _____ Fax Number: _____ c. Fax _____ Fax Number: _____ d. Phone only _____ Phone No.: _____ e. Supplier Web Site only _____ Site Address: _____ Minimum Order Quantity: _____ Units Supplier's Customer Service Number: _____ Contracted 3PL company / contact #: _____ Name: _____ Phone: _____	Purchase order daily receipt cut off time by supplier Cut off time: _____ Shipping lead time of PO: _____ Hours _____ Days Ships same day for next day receipt: _____ Ships for second day receipt: _____ Ships regular ground for 3-10 days receipt: _____
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: _____ Drop Ship service fee billed with each order: _____ Drop Ship miscellaneous fees billed: _____ Comments: _____	Overnight receipt available: _____ PO Receipt cut off time: _____ 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: _____ PO Receipt Cut off time: _____
Class of Trade Restriction:	Saturday Overnight receipt available:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices _____ Restricted to retail pharmacy only: _____ Restricted to hospital, clinics, and physician offices only: _____ Restricted from US territories? (explain in comments) _____ Comments: _____	Saturday Overnight receipt available: _____ PO Receipt Cut off time: _____ Order receipt method: Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ Overnight Fees apply: _____ Other fees apply: _____
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____	Contact # if product is 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:	ADDITIONAL INFORMATION
_____	Is product order for scheduled patient procedure? _____ Is product order for restocking purposes? _____