



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="075317"/>				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="Terazosin HCl Capsules"/>		Unit of Use NDC: <input type="text" value="3-59746-385-10-1"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Selling Unit NDC: <input type="text" value="59746-385-10"/>		UPC: <input type="text"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>			
UDI: <input type="text"/>		CVX Code: <input type="text"/>					
MVX Code: <input type="text"/>							
Description: <input type="text" value="Terazosin Hydrochloride 5mg 1000ct Capsules"/>				b. Contact for temperature excursion questions:			
Active Ingredient(s): <input type="text" value="Terazosin 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="Benign Prostatic Hypertrophy"/>		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="1000 count"/>					
if yes, enter class # a product kit? <input type="text"/>	Is the Product... Neither <input type="text"/>	Strength: <input type="text" value="5mg"/>					
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	Orphan Drug Status <input type="text"/>	Dosage Form: <input type="text" value="CAPSULE"/>					
co-licensed? <input type="text"/>	FDA Approval Status <input type="text"/>	Product Shape: <input type="text" value="Capsule, Size 3"/>					
latex-free? <input type="text"/>	Allergens Present <input type="text"/>	Product Color: <input type="text" value="Orange"/>					
preservative-free? <input type="text"/>	Country of Origin <input type="text" value="US"/>	Product Imprint: <input type="text" value="TL 385"/>					
correctional institution block? <input type="text"/>	Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>						
opioid? <input type="text"/>							
Cannabinoid? <input type="text"/>							
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"/>							
ORDER INFORMATION							
Unit of Sale			What is the NDC selling unit?				
<input checked="" type="checkbox"/> Bottle			<input type="text" value="1 bottle of 1000 capsules"/>				
<input type="checkbox"/> Box/Carton			(Write-in, e.g. 1 Box of 10 Vials)				
<input type="checkbox"/> Ampule			Minimum order quantity? <input type="text" value="Yes"/>				
<input type="checkbox"/> Glass							
<input type="checkbox"/> Tube			If Yes, how many of which package type?				
<input type="checkbox"/> Vial Liquid Sgl			<input type="text" value="12"/> Each				
<input type="checkbox"/> Vial Liquid Multi			<input type="text"/>				
<input type="checkbox"/> Vial Powder Sgl			Inner/Carton/Pack				
<input type="checkbox"/> Vial Power Multi			Case				
<input type="checkbox"/> Other: Write In							
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="Hytrin"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="0359746000004"/>					
Is product exempt from DSCSA? <input type="text" value="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="text"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Is product repackaged? <input type="text"/>							
Is product sold by manufacturer's exclusive distributor? <input type="text"/>							
Has FDA granted waiver/exception/exemption for product? <input type="text"/>							
If yes, attach documentation from FDA. <input type="text"/>							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.66	3.5	3.5	6.3	77.18	1	
Box/Carton/Bundle/Inner Pack:					0.00		
Case:	8.53	14.25	10.75	7	1072.31	12	
Pallet:					0.00		
GTIN AND HIBCC PRODUCT INFORMATION			COST 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" value="00359746385101"/>				
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack							
<input checked="" type="checkbox"/> Case	<input type="text" value="12"/>		<input type="text" value="40359746385109"/>				
<input type="checkbox"/> Pallet							
WHOLESALE USE ONLY:			Regular Cost				
Invoice Cost (WAC) (\$)			<input type="text" value="\$176.40"/>				
As of date: <input type="text"/>			Vendor #: <input type="text"/>				
			Whsl. Code #: <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: <input type="text"/>			



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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? (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) No
- 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) No
- 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 Controlled Substance Code
 - Controlled by State(s)? No Listed Chemical (List I or II) No
 - ARCOS Reportable? No 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
- 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?



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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:	
<p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>