



# 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				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc.		Application: 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): 075317				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: 022490515				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: Terazosin HCl Capsules				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: 59746-383-06		Unit of Use NDC:		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
UDI:		CVX Code:					
Description: Terazosin Hydrochloride 1mg 100ct Capsules		UPC: 3-59746-383-06-0					
Active Ingredient(s): Terazosin Hydrochloride		MVX Code:					
URL for Additional Product Information: <a href="http://www.cadista.com/products/full-product-list">www.cadista.com/products/full-product-list</a>				<b>b. Contact for temperature excursion questions:</b>			
Address: 790 Township Line Road		Address 2: Suite 325		Name: Customer Service			
City: Yardley		State: PA		Number: (800) 313-4623			
Key Contact: Customer Service		Zip: 19067		Group E-mail: <a href="mailto:customer.service@cadista.com">customer.service@cadista.com</a>			
Phone Number: (800) 313-4623		Fax: N/A					
Product Therapeutic Classification: Benign Prostatic Hypertrophy				<b>c. Special regulations for product in any states?</b>			
				Special returns requirements for this product? <input type="checkbox"/> No			
				<b>d. Store product (unit of sale) upright?</b>			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				<b>e. Shelf life:</b>			
				Initial shelf life at launch (if different): <input type="text" value="24"/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is a legend device? <input type="checkbox"/> No		Is the Product... Direct-Ship Only <input type="checkbox"/>		Size: 100 count			
if yes, enter class # a product kit? <input type="checkbox"/> No		Is the Product... Neither <input type="checkbox"/>		Strength: 1mg			
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No		Orphan Drug Status <input type="checkbox"/>		Dosage Form: CAPSULE			
co-licensed? <input type="checkbox"/> No		FDA Approval Status <input type="text"/>		Product Shape: Capsule, Size 3			
latex-free? <input type="checkbox"/> Yes		Allergens Present <input type="text"/>		Product Color: Iron Grey			
preservative-free? <input type="checkbox"/> No		Country of Origin: US <input type="checkbox"/>		Product Imprint: TL 383			
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"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes					
If Unit Dose, indicate NDC here: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB <input type="text"/>		<input type="checkbox"/> Authorized Generic		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Hytrin®							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: 0359746000004					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: 0359746					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <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. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		1				00359746383060	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack							
<input checked="" type="checkbox"/> Case		24				40359746383068	
<input type="checkbox"/> Pallet							
Unit of Use GTIN-14							
ORDER INFORMATION				PHARMACY ORDER / BILL UNIT			
Unit of Sale		What is the NDC selling unit?		Rec. sell unit to customer?			
<input checked="" type="checkbox"/> Bottle		1 bottle of 100 capsules		1 bottle of 100 capsules			
<input type="checkbox"/> Box/ Carton		(Write-in, e.g. 1 Box of 10 Vials)		Rx billing unit to pharmacy:			
<input type="checkbox"/> Ampule				<input checked="" type="checkbox"/> Each			
<input type="checkbox"/> Glass				<input type="checkbox"/> Gram			
<input type="checkbox"/> Tube				Minimum order quantity? <input type="checkbox"/> Yes			
<input type="checkbox"/> Vial Liquid Sgl				If Yes, how many of which package type?			
<input type="checkbox"/> Vial Liquid Multi				24 Each			
<input type="checkbox"/> Vial Powder Sgl				Inner/ Carton/ Pack			
<input type="checkbox"/> Vial Power Multi				Case			
Other: Write In <input type="text"/>							
ITEM AND PACKING INFORMATION							
		Weight Lbs.		Dimensions (US msmts.)		Volume Saleable #	
				Depth Width Height		(Cube) Pieces	
Item/Each:		0.12		1.9 1.9 4		14.44 1	
Box/ Carton/ Bundle/ Inner Pack:						0.00	
Case:		3.31		11.75 8 5.25		493.50 24	
Pallet:						0.00	
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)		\$18.00		Whsl. Code #:			
As of date:				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: <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?
  - 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:

