



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  New Drug  Post Launch Change Final Version

Date: 1/18/2021

PRODUCT INFORMATION	
Company Name:	Jubilant Cadista Pharmaceuticals Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	A75317
DUNS:	022490515
Proprietary Name (If Applicable) and Established Name:	Terazosin Hydrochloride Capsules
Selling Unit NDC:	59746-0384-06
UDI	
CVX Code:	
UPC:	3-59746-384-06-7
MXV Code:	
Description:	Terazosin Hydrochloride 2mg 100ct Capsules
Active Ingredient(s):	Terazosin
URL for Additional Product Information:	www.cadista.com
Address:	207 Kiley Drive
City:	Salisbury
Key Contact:	Jackie Emershaw
Phone Number:	(410) 912-3722
Product Therapeutic Classification:	Benign Prostatic Hypertrophy

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° F)
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:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	Yes
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only?	
Is the Product... Direct-Ship Only?	
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)?	Yes

PRODUCT DESCRIPTION INFORMATION	
Size:	100ct
Strength:	2mg
Dosage Form:	CAP
Product Shape:	SIZE 3 CAPSULE
Product Color:	ivory opaque
Product Imprint:	TL 384

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Case of 24 bottles
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	24 Each
	Inner/ Carton/ Pack
	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	HYTRIN
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Each
	Gram
	Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
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
GLN:	0359746000004
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:					0	
Case:	3.31	11.75	5.25	8	491.5	24
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION										
Serialized?	If not, when?	Items aggregated?	Level	Saleable Unit		Quantity	GTIN-14	2D	Linear	2D
				Item	Box/ Carton/ Bundle/ Inner Pack					
<input checked="" type="checkbox"/>			Case	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	24	40359746384065	<input checked="" type="checkbox"/>		
			Pallet							

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$18.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

\*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?

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:  (410) 912-3722

Is product returnable for credit:

URL/Link to returns policy:  www.cadista.com

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:**

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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/></td> <td style="width: 10%; text-align: center;">Yes</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td colspan="3" style="border: 1px solid black; height: 15px;"></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Yes</td> <td>Fax Number:</td> <td colspan="3" style="border: 1px solid black; height: 15px;"></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Phone No.:</td> <td colspan="3" style="border: 1px solid black; height: 15px;"></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td>Site Address:</td> <td colspan="3" style="border: 1px solid black; height: 15px;"></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 50px;" type="text" value="24"/></p> <p>Supplier's Customer Service Number: <input style="width: 80%;" type="text" value="(410) 912-3722"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td style="border: 1px solid black; height: 15px;"></td> </tr> <tr> <td>Phone:</td> <td style="border: 1px solid black; height: 15px;"></td> </tr> </table>	a. EDI	<input type="checkbox"/>	Yes					b. Autofax	<input type="checkbox"/>	Yes	Fax Number:				c. Fax	<input type="checkbox"/>	Yes	Fax Number:				d. Phone only	<input type="checkbox"/>		Phone No.:				e. Supplier Web Site only	<input type="checkbox"/>		Site Address:				Name:		Phone:		<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 150px;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 40px;" type="text"/> Hours <input style="width: 40px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 40px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 40px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 40px;" type="text"/></p>
a. EDI	<input type="checkbox"/>	Yes																																						
b. Autofax	<input type="checkbox"/>	Yes	Fax Number:																																					
c. Fax	<input type="checkbox"/>	Yes	Fax Number:																																					
d. Phone only	<input type="checkbox"/>		Phone No.:																																					
e. Supplier Web Site only	<input type="checkbox"/>		Site Address:																																					
Name:																																								
Phone:																																								
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																							
<p>Expedited freight fees billed with each order: <input style="width: 60px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 60px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 60px;" type="text"/></p> <p>Comments: <div style="border: 1px solid black; height: 80px; width: 100%;"></div></p>	<p><b>Overnight receipt available:</b> <input style="width: 40px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input style="width: 40px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 40px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Phone:</td> <td style="width: 15%; border: 1px solid black; height: 15px;"></td> <td style="width: 15%;">Phone #:</td> <td style="width: 15%; border: 1px solid black; height: 15px;"></td> </tr> <tr> <td>Fax:</td> <td style="border: 1px solid black; height: 15px;"></td> <td>Fax #:</td> <td style="border: 1px solid black; height: 15px;"></td> </tr> <tr> <td>EDI:</td> <td style="border: 1px solid black; height: 15px;"></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input style="width: 40px;" type="text"/></p> <p>Other fees apply: <input style="width: 40px;" type="text"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:		Phone #:		Fax:		Fax #:		EDI:																				
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Fax:		Fax #:																																						
EDI:																																								
Class of Trade Restriction:	Return Instructions																																							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 40px;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 40px;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 40px;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 40px;" type="text"/></p> <p>Comments: <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>	<p>Contact # if product is received damaged: <input style="width: 100px;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 40px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 150px;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 40px;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>																																							
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																							
<p>Patient Procedure Date: <input style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 150px;" type="text"/></p> <p>Physician State License #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 250px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 40px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 40px;" type="text"/></p>																																							
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