



# 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 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 Salisbury Key Contact: Jackie Emershaw Phone Number: (410) 912-3722
State:	MD
Zip:	21801
Email:	Jackie.Emershaw@cadista.com
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:	
Initial shelf life at launch (if different):	24 Months
	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)?	

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	Minimum order quantity? Yes
<input type="checkbox"/> Tube	
<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
<input type="checkbox"/> Other: Write In	

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
	<input type="checkbox"/> Gram
	<input type="checkbox"/> 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:	
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		
Item:	0.118	1.5	3.80	2	11.4	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	2.86	12.25	4.5	8.25	454.78	24
Pallet:					0	
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION			
Serialized?	Yes		
If not, when?			
Items aggregated?			
Level	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/> 2D	1	00359746384067
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/> 2D		
<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/> 2D	24	40359746384065
<input type="checkbox"/> Pallet	<input type="checkbox"/> 2D		
	<input type="checkbox"/> 2D		
	<input type="checkbox"/> 2D		
	<input type="checkbox"/> 2D		
	<input type="checkbox"/> 2D		
	<input type="checkbox"/> 2D		
	<input type="checkbox"/> 2D		
	<input type="checkbox"/> 2D		
	<input type="checkbox"/> 2D		

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:			

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

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> 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:

