



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021		Introduction Type: Post Launch Change		x Final Version		Date: 7/12/2021																																								
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																								
<div>Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA</div> <div>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 075317</div> <div>Medical Device Class, if applicable:</div> <div>DUNS: 022490515</div> <div>Proprietary Name (If Applicable) and Established Name: Terazosin HCl Capsules</div> <div>Selling Unit NDC: 59746-385-06 Unit of Use NDC: UPC: 3-59746-385-06-4</div> <div>UDI: CVX Code: MVX Code:</div> <div>Description: Terazosin Hydrochloride 5mg 100ct Capsules</div> <div>Active Ingredient(s): Terazosin Hydrochloride</div> <div>URL for Additional Product Information: www.cadista.com/products/full-product-list</div> <div>Address: 207 Kiley Drive Salisbury Key Contact: Jackie Emershaw Phone Number: (410) 912-3722</div> <div>State: MD Zip: 21801 Email: Jackie.Emershaw@jubil.com Fax: (215) - 443 - 9646</div> <div>Product Therapeutic Classification: Benign Prostatic Hypertrophy</div>						<div>a. Temperature – Indicate the USP temperature range for this product.</div> <div>Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)</div> <div>Other Temperature Range Requirement (write in):</div> <div>Notes:</div> <div>Is this product to be shipped to customers on ice? No</div> <div>Is this product to be shipped to customers on dry ice? No</div> <div>b. Contact for temperature excursion questions:</div> <div>Name: Customer Service</div> <div>Number: (800) 313-4623</div> <div>Group E-mail: customer.service@cadista.com</div> <div>c. Special regulations for product in any states?</div> <div>Special returns requirements for this product? No</div> <div>d. Store product (unit of sale) upright? No</div> <div>Protect product (unit of sale) from light? No</div> <div>e. Shelf life:</div> <div>Initial shelf life at launch (if different): 24 Months</div>																																								
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																										
<div>The product is? No</div> <div>a legend device? No</div> <div>if yes, enter class #</div> <div>a product kit? No</div> <div>if yes, list NDCs of component parts</div> <div>reverse numbered? No</div> <div>co-licensed? No</div> <div>latex-free? Yes</div> <div>preservative-free? No</div> <div>correctional institution block? Yes</div> <div>opioid? No</div> <div>Cannabinoid? No</div> <div>If Unit Dose, is item bar coded to unit dose for hospital scanning?</div> <div>If Unit Dose, indicate NDC here:</div> <div>Is the Product... Direct-Ship Only No</div> <div>Is the Product... Neither</div> <div>Orphan Drug Status</div> <div>FDA Approval Status</div> <div>Allergens Present</div> <div>Country of Origin: US</div> <div>Is this product covered under the Trade Agreements Act (TAA)? Yes</div>				<div>Size: 100 count</div> <div>Strength: 5mg</div> <div>Dosage Form: CAPSULE</div> <div>Product Shape: Capsule, Size 3</div> <div>Product Color: Orange</div> <div>Product Imprint: TL 385</div>																																										
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION																																								
<div>I. Orange Book Rating: AB</div> <div>II. Generic Equivalent to What Brand?: Hytrin</div> <div>Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable</div>						<div>Unit of Sale</div> <table border="1"><tr><td>X</td><td>Bottle</td></tr><tr><td></td><td>Box/ Carton</td></tr><tr><td></td><td>Ampule</td></tr><tr><td></td><td>Glass</td></tr><tr><td></td><td>Tube</td></tr><tr><td></td><td>Vial Liquid Sgl</td></tr><tr><td></td><td>Vial Liquid Multi</td></tr><tr><td></td><td>Vial Powder Sgl</td></tr><tr><td></td><td>Vial Powder Multi</td></tr><tr><td></td><td>Other: Write In</td></tr></table> <div>What is the NDC selling unit?</div> <div>1 bottle of 100 capsules</div> <div>(Write-in, e.g. 1 Box of 10 Vials)</div> <div>Minimum order quantity? Yes</div> <div>If Yes, how many of which package type?</div> <div>24 Each</div> <div>Inner/ Carton/ Pack</div> <div>Case</div>		X	Bottle		Box/ Carton		Ampule		Glass		Tube		Vial Liquid Sgl		Vial Liquid Multi		Vial Powder Sgl		Vial Powder Multi		Other: Write In																			
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DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						PHARMACY ORDER / BILL UNIT																																								
<div>Does supplier meet DSCSA definition of manufacturer? Yes</div> <div>Is product exempt from DSCSA? No</div> <div>If yes, select exemption:</div> <div>Other exemption - Write in:</div> <div>Is product repackaged? No</div> <div>Is product sold by manufacturer's exclusive distributor? No</div> <div>Has FDA granted waiver/exception/exemption for product? No</div> <div>If yes, attach documentation from FDA.</div> <div>GLN: 0359746000004</div> <div>GCP: 0359746</div> <div>If yes, was original product purchased direct from mfr? No</div> <div>Provide source manufacturer for repackaged product</div>						<div>Rec. sell unit to customer?</div> <div>1 bottle of 100 capsules</div> <div>(Write-in, e.g. 1 Vial)</div> <div>Rx billing unit to pharmacy:</div> <div>X Each</div> <div>Gram</div> <div>Milliliter</div>																																								
GTIN AND HIBCC PRODUCT INFORMATION						ITEM AND PACKING INFORMATION																																								
<div>Saleable Unit of Measure</div> <table border="1"><tr><td>X</td><td>Item/Each</td></tr><tr><td></td><td>Box/ Carton/ Bundle/ Inner Pack</td></tr><tr><td>X</td><td>Case</td></tr><tr><td></td><td>Pallet</td></tr></table> <div>Saleable Quantity</div> <div>1</div> <div>24</div> <div>HIBCC</div> <div>GTIN-14</div> <div>00359746385064</div> <div>40359746385062</div> <div>Unit of Use GTIN-14</div>						X	Item/Each		Box/ Carton/ Bundle/ Inner Pack	X	Case		Pallet	<table border="1"><thead><tr><th rowspan="2">Item/Each:</th><th rowspan="2">Weight Lbs.</th><th colspan="3">Dimensions (US msmts.)</th><th rowspan="2">Volume (Cube)</th><th rowspan="2">Saleable # Pieces</th></tr><tr><th>Depth</th><th>Width</th><th>Height</th></tr></thead><tbody><tr><td>Box/ Carton/ Bundle/ Inner Pack:</td><td>0.13</td><td>1.9</td><td>1.9</td><td>4</td><td>14.44</td><td>1</td></tr><tr><td>Case:</td><td>3.42</td><td>11.5</td><td>7.75</td><td>5</td><td>445.63</td><td>24</td></tr><tr><td>Pallet:</td><td></td><td></td><td></td><td></td><td>0.00</td><td></td></tr></tbody></table>		Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	Depth	Width	Height	Box/ Carton/ Bundle/ Inner Pack:	0.13	1.9	1.9	4	14.44	1	Case:	3.42	11.5	7.75	5	445.63	24	Pallet:					0.00	
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COST INFORMATION						WHOLESALE USE ONLY:																																								
<div>Regular Cost</div> <div>Invoice Cost (WAC) (\$)</div> <div>As of date:</div>						<div>Vendor #:</div> <div>Whsl. Code #:</div> <div>Fineline Code:</div>																																								
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.						Signature:																																								
*Please provide any additional information on page 2.						See new p. 3 for Designated Drop Ship Only.																																								



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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?	<input type="checkbox"/> No		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?			
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/> No		
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/> No		
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/> No		
c. Contact Hazard?	<input type="checkbox"/> No		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/> No		
e. Does the product contain DEHP?	<input type="checkbox"/> 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?	<input type="checkbox"/> 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?	<input type="checkbox"/> No		
Is the product restricted for air shipment? If so, indicate restriction:		<input type="checkbox"/> No	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
Is this a reportable quantity? <input type="checkbox"/> No			
RQ Threshold:			
Is this a marine pollutant? <input type="checkbox"/> No			
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
<input type="checkbox"/> No	(if yes, identify method below)		
<input type="checkbox"/> Limited Quantity			
<input type="checkbox"/> Consumer Commodity, ORM-D			
<input type="checkbox"/> Small Quantity (49 CFR 173.4)			
<input type="checkbox"/> Special Permit, DOT-SP			
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP#			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="checkbox"/> Yes	
Restricted to retail pharmacy only:		<input type="checkbox"/>	
Restricted to hospital, clinics, and physician offices only:		<input type="checkbox"/>	
Restricted from US territories? (explain in comments)		<input type="checkbox"/>	
Comments:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

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
Does the product have an Aerosol class? If yes, identify <input type="checkbox"/> No	
NFPA Storage Level: <input type="text"/>	
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <input type="checkbox"/> No	
If yes, indicate which: <input type="text"/>	

Hazardous Waste Identification	
EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <input type="checkbox"/> No	
If Yes, is it managed with a pharmacy registry? <input type="checkbox"/>	
Website URL: <input type="text"/>	
Med Guide Required	<input type="checkbox"/> No
Limited Distribution Requirement	<input type="checkbox"/> No
Comments / Details: (For example, iPledge program?) <input type="text"/>	
REMS:	
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="checkbox"/>
Wholesale distributor support:	<input type="checkbox"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text"/>
Registry:	
Registry Program Contact Name:	<input type="text"/>
Phone:	<input type="text"/>
Comments	<input type="text"/>

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <input type="text"/>	
Is product returnable for credit: <input type="checkbox"/>	
URL/Link to returns policy: <input type="text"/>	
Special regulations or returns requirements for this product in certain states? <input type="checkbox"/>	
If so, which states? Other requirements? Comments? <input type="text"/>	



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