

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

						Introduction Type	: Post Launch Change		x Final Version			Date:	7/12/	2021
			PRODUCT INFORMAT	TION					SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 075317										n – between 20 and 25 C (68° – 77° F)				
Medical Device Class, if applical														
DUNS:	022490515							Ot	ther Temperature Range R	equirement				
Proprietary Name (If Applicable) a	nd Established N	ame: Terazos	sin HCl Capsules						(write in)					
Selling Unit NDC:	59746-384-06		Unit of Use NDC:			UPC: 3-5	9746-384-06-7	No	otes					
UDI			CVX Code:			MVX Code:								
Description: Terazosin Hydrochloride 2mg 100ct Capsulles Is this produ										to customers on i	ce?		No	
	, ,	, J							this product to be shipped				No	
Active Ingredient(s): Terazosin Hydrochloride											,	1		
								b. Contact for temperature excursion questions:						
URL for Additional Product Information: <u>www.cadista.com/products/full-product-list</u>						Name: Customer Service				ervice				
Address:	207 Kiley Drive					Address 2:		Nu	umber:		(800) 313-46	23		
City:	Salisbury				State:		p : 21801	Gı	roup E-mail:		customer.	service@ca	dista.com	
Key Contact:	Jackie Emershaw	<u>'</u>			Email:	Jackie.Emershaw@	<u>Pjubl.com</u>							
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646			ations for product in any				No	
Product Therapeutic Classification	n:	Benign Prostatic Hyp	ertrophy					Sp	pecial returns requirements	s for this product?			No	
								_						
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only			Pr	rotect product (unit of sal	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			OILC.		Ini	itial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	2mg							
if yes, list NDCs of			FDA Approval Status			3				ORDER INFORM	IATION			
component parts						Dosage Form:	CAPSULE				140 (! - (! -	NDO III		
reverse numbered?		No						Ui	nit of Sale X Bottle		What is the		unit?	
co-licensed? latex-free?		No	Allergens Present				Canada Cina 2	_	Box/Carton		1 bottle of 10		\/iala\	
preservative-free?		Yes No				Product Shape:	Capsule, Size 3		Ampule		(vviite-in, e.	g. 1 Box of 10	viais)	
correctional institution block?		Yes					Ivory		Glass		Minimum o	der quantity	,	Yes
opioid?		No				Product Color:	ivoly		Tube		MILLION OF	uci quantity		103
Cannabinoid?		No	Country of Origin	US			TL 384		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for	140	,g			Product Imprint:			Vial Liquid Multi		If Yes, how	manv of whi	h package	type?
hospital scanning?	4000 101		Is this product covered up	nder the					Vial Powder Sql		24	Each		71
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		Yes				Vial Power Multi			Inner/Carton	Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS										
			,					7						
					Au	thorized Generic *If	Authorized Generic, other		PHA	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB												cv.	
	AD					sec	ction fields are not applicable	Rec. sell unit to	customer?		Rx billing u	nit to pharma		
II. Generic Equivalent to What Bra		Hytrin				sec	ction fields are not applicable	Rec. sell unit to d			Rx billing u		oy.	
II. Generic Equivalent to What Bra		Hytrin				sec	tion fields are not applicable	1 bottle	of 100 capsules			nit to pharma Each Gram		
II. Generic Equivalent to What Bra			′ CHAIN SECURITY ACT ([DSCSA) INFOR	RMATION	Sec	tion fields are not applicable	_	of 100 capsules			Each		
II. Generic Equivalent to What Bra			CHAIN SECURITY ACT (E	DSCSA) INFOR	RMATION	Sec	tion fields are not applicable	1 bottle	of 100 capsules Vial)		X	Each Gram Milliliter	oy.	
Does supplier meet DSCSA defini	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR	RMATION GLN:	0359746000004	tion fields are not applicable	1 bottle	of 100 capsules Vial)	AND PACKING IN	X	Each Gram Milliliter	oy.	
	nd?:	DRUG SUPPLY		DSCSA) INFOR			tion fields are not applicable	1 bottle	of 100 capsules Vial)	AND PACKING IN	X	Each Gram Milliliter		
Does supplier meet DSCSA defini	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR			tion fields are not applicable	1 bottle	of 100 capsules Vial)		X	Each Gram Milliliter	Volume	Saleable #
Does supplier meet DSCSA defini	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR	GLN:	0359746000004	fields are not applicable	1 bottle	of 100 capsules Vial)		X	Each Gram Milliliter		Saleable #
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR	GLN:	0359746000004 0359746	fields are not applicable	1 bottle	of 100 capsules Vial) ITEM Weight Lbs.	Dimensi Depth	NFORMATION ons (US msn Width	Each Gram Milliliter	Volume (Cube)	Pieces
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?: tion of manufactu	DRUG SUPPLY	Yes No No	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	0359746000004 0359746 iginal product rect from mfr?		1 bottle (Write-in, e.g. 1 \	of 100 capsules Vial) ITEM Weight Lbs. 0.12	Dimensi	X NFORMATION ons (US msn	Each Gram Milliliter	Volume	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nd?: tion of manufactu exclusive distribn/exemption for p	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	0359746000004 0359746 iginal product		1 bottle (Write-in, e.g. 1 \) Item/Each: Box/Carton/Bund	of 100 capsules Vial) ITEM Weight Lbs. 0.12	Dimensi Depth	NFORMATION ons (US msn Width	Each Gram Milliliter	Volume (Cube)	Pieces
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Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X	nd?: tion of manufactu exclusive distrib n/exemption for p n FDA.	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity	Yes No No No No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased di Provide source GTII	0359746000004 0359746 iginal product rect from mfr? remanufacturer for re	packaged product	1 bottle (Write-in, e.g. 1 \text{ V} Item/Each: Box/Carton/Bund Inner Pack: Case:	of 100 capsules Vial) Weight Lbs. 0.12	Dimensi Depth 1.9	X WFORMATION ONS (US msm Width 1.9 7.75	Each Gram Milliliter Ats.) Height	Volume (Cube) 14.44 0.00 445.63 0.00	Pieces 1 24
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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 SDS Hazard Classification b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No c. Contact Hazard? No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number Is there a REMS on this product? b. Proper Shipping Name c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Med Guide Required No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Site Enrollment Number assigned NCPDP# Limited Quantity Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS 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: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



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Version 2021

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					
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:					
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:	Overnight receipt available:					
Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday Priority Overnight receipt available:					
Class of Trade Restriction:	PO Receipt Cut off time:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is 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?					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure? Is product order for restocking purposes?					