

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

Version 2021							Introduction T	Гуре:	Post Launch Change		x F	inal Version			Date:	7/12	/2021
				PRODUCT INFORMA	TION			1				SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.										
						Controlled Room		and 25 C (68	3° – 77° F)								
Medical Device Class, if applica	ble:											-					
DUNS:	022490515									4	Other Temp	perature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	ame:	Terazosi	n HCI Capsules						]	(write	in)					
Selling Unit NDC:	59746-383-06			Unit of Use NDC	:		UPC:	3-59746-38	33-06-0		Notes						
UDI	UDI CVX Code: MVX					MVX Code:											
Description: Terazosin Hydrochloride 1mg 100ct Capsules							1	Is this prod	uct to be shippe	d to customers on i	ce?		No	]			
								Is this prod	uct to be shippe	d to customers on o	Iry ice?		No				
Active Ingredient(s): Terazosin Hydrochloride																	
URL for Additional Product Information: www.cadista.com/products/full-product-list								b. Contact for temperature excursion questions: Name:				Customer Service					
Address:	207 Kiley Drive					Address 2:			Number:				(800) 313-4623				
City:	Salisbury					MD	<b>Zip:</b> 21	801	Group E-mail:					service@ca	adista.com		
Key Contact:	Jackie Emershaw					Jackie.Emersha	aw@jubl.c	om									
Phone Number:	(410) 912-3722					(215) - 443 - 9646	6		c. Special regulations for product in any states? No					]			
Product Therapeutic Classificatio	n:	Benign Prostatic Hypertrophy							Special returns requirements for this product? No					]			
	ADDITI	ONAL PRODU	JCT INFO	RMATION			PRODUCT D	DESCRIPTIC	ON INFORMATION	d. Store proc	duct (unit of s	sale) upright?				No	
The product is?			_	Is the Product	Direct-Ship	Only					Protect pro	oduct (unit of s	ale) from light?			No	]
a legend device?		No		Is the Product	Neither		Size:	100	count	e. Shelf life:						24	Months
if yes, enter class #		1		Orphan Drug Status							Initial shelf	f life at launch	if different):				Months
a product kit?		No		FDA A			Strength:	1mg	1								
if yes, list NDCs of component parts				FDA Approval Status				CAL	SULE					IATION			
reverse numbered?		No					Dosage Forn	n:	JULL		Unit of Sal	e		What is the	NDC selling	unit?	
co-licensed?		No		Allergens Present								ottle		1 bottle of 1			
latex-free?		Yes					Desident Obse	Cap	sule, Size 3			ox/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)	
preservative-free?		No					Product Sha	ipe:			A	mpule			•		
correctional institution block?		Yes	]				Product Cold	Iron	Grey			ilass		Minimum o	rder quantity	/?	Yes
opioid?		No					i iouuci oolo					ube					
Cannabinoid?		No	]	Country of Origin	US		Product Imp	rint: TL 3	383			ial Liquid Sgl					
If Unit Dose, is item bar coded to u hospital scanning?	unit dose for		1	Is this product covered	under the		-					ial Liquid Multi ial Powder Sql		If Yes, how 24	many of wh Each	ich package	type?
If Unit Dose, indicate NDC here:				Trade Agreements Act		Yes						ial Power Multi		24	Inner/Cartor	/Pack	
in onit bose, indicate rabe nere.				J	, , , , , , , , , , , , , , , , , , ,	103						ther: Write In			Case	in dok	
			F	OR GENERIC DRUG PR	ODUCTS		4								1		
										-							
						A	uthorized Generic		ed Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AB							section fields are not applicable Rec. sell uni				unit to customer? Rx billing unit to pharmacy:				acy:	
II. Generic Equivalent to What Brand?: Hytrin							1 bottle of 100 capsules				X Each						
						(Write-in, e.g. 1 Vial)					Gram						
		DRUG	SUPPLY	CHAIN SECURITY ACT	(DSCSA) INFO	RMATION				_					Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	ror?		Yes		GLN:	0359746000004					ITEN	I AND PACKING I	FORMATIO	N		
Is product exempt from DSCSA?				No	-	GEN.	00000004										
						GCP:	0359746			1			Dimonei	ons (US msr	nts)	Volume	Saleable #
If yes, select exemption: Other exemption - Write in:						GUF.	0000140			1		Weight Lbs.	Depth	Width	Height	(Cube)	Saleable # Pieces
Is product repackaged?				No		If yes, was o	riginal product			Item/Each:		0.42					, , ,
Is product sold by manufacturer's	exclusive distribute	utor?		No			lirect from mfr?					0.13	1.9	1.9	4	14.44	1
Has FDA granted waiver/exceptio	n/exemption for p			No		Provide sour	rce manufacturer fo	or repackag	ed product	Box/Carton/E	Bundle/					0.00	
If yes, attach documentation from	m FDA.									Inner Pack:						0.00	
			CTIN /	AND HIBCC PRODUCT						Case:		3.42	11.5	7.75	5	445.63	24
			GTIN		INFORMATION					Pallet:							
Saleable Unit of Measure		Saleable Quan	titv	HIBCC		GT	IN-14	Ur	it of Use GTIN-14	Fallet.						0.00	
X Item/Each	e e	1	1			_	359746383060										
Box/Carton/Bundle/Inner Pack									COST I	NFORMATION			WHOLESAL	ER USE ONL	Y:		
X Case		24	]			403	359746383068										
Pallet	-									Regular Cos				Vendor #:			
	_					_		_		Invoice Cost	(WAC) (\$)		\$18.00	Whsl. Code			
	-					_		-			-			Fineline Co	de:		
	-							-		As of date:							
			1														
<u> </u>			Δ.	ttach copy of SAFETY D.	ATA SHEET /ST	S) or non haza		INSERT 1			AGING and F	BARCODE		1			
*Please provide any additional inf	formation on name	2	A	adon copy of OAFEIT D	UN ONEET (OL	Joj or non ndZa			I Drop Ship Only.	NODUCI FACK	Signature:						
	eauon on page						000 non p. 0 101	- soignatet			orginatare.						

## **HDA** Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 For Desig	nated 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? 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.) e. Does the product contain DEHP? No (If yes, answer a-e below and provide SDS) a. UN/Identification Number	SDS Hazard Classification         Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes, identify       No         NFPA Storage Level:       NFPA Storage Level:         Is the product a NIOSH hazardous drug?       No         If yes, indicate which:       No						
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by 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? No 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 Pervision (listed in Column 7 of 49 CFR 172.101); SP#	Med Guide Required     No       Limited Distribution Requirement     No       Comments / Details: (For example, iPledge program?)     No       REMS:     Phone:       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:						
ADD'L STORAGE INFORMATION Is the Product Controlled Substance? No Controlled Substance Code	Comments RETURN INSTRUCTIONS						
Controlled by State(s)?       No       Listed Chemical (List I or II)       No         ARCOS Reportable?       No       If yes, indicate which:       If yes, indicate which:       If yes, indicate which:         Schedule No.       Is it a scheduled listed chemical product?:       No         CLASS OF TRADE RESTRICTION:         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:	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?						
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:						



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

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:         PO Receipt cut off time:         Days of week overnight is available:         Monday         Tuesday         Wednesday         Thursday         Friday
Class of Trade Restriction:	Priority Overnight receipt available: 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)	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION  Is product order for scheduled patient procedure? Is product order for restocking purposes?