

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

Version 2024						Introduction T	ype:		Final Version			Date:	2/24	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	IDA/BLA; PMA/510	(k): 075317				NDA 505(b) Type:			Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat	ble:													
DUNS:	118694141								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Terazos	sin HCI Capsules						(write in)					
Selling Unit NDC:	59746-383-10		Unit of Use NDC:			UPC:	3-59746-383-10-7	1	Notes					
UDI			CVX Code:			MVX Code:								
Description:	Terazosin Hydroc	hloride 1mg 1000ct Ca	apsules						s this product to be shippe				No	
Active Ingredient(s):		Terazosin Hydrochlo	ride						s this product to be shippe		ary ice?		No	
URL for Additional Product Inform	nation:	www.cadista.com	n/products/full-product	t-list					Name:	estions.	Customer S	ervice		
Address:	790 Township Lin		i producto run product	<u>e noe</u>		Address 2:	Suite 325		Number:		(800) 313-46			
City:	Yardley				State:	PA	Zip: 19067		Group E-mail:		customer.	service@ca	dista.com	
Key Contact:	Customer Service	•			Email:	customer.serv	ce@cadista.com							
Phone Number:	(800) 313-4623				Fax:	N/A		c. Special regu	lations for product in any	states?			No	
Product Therapeutic Classification	on:	Benign Prostatic Hyp	ertrophy					S	Special returns requiremen	ts for this product?			No	
		ONAL PRODUCT INF				PRODUCT	DESCRIPTION INFORMATION	d Store produc	ct (unit of sale) upright?				No	1
The sea hard in 0				Direct Chin C	where the second s	1 10000011		-		1.) (1
The product is? a legend device?		N	Is the Product Is the Product	Direct-Ship C Neither	iniy		1000 count	e. Shelf life:	Protect product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #		No	Orphan Drug Status	Ineluter		Size:	1000 count	111	nitial shelf life at launch (if different).			24	Months
a product kit?		No	orphan brug status				1mg	- H		in unierenty.				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts						B	CAPSULE							
reverse numbered?		No				Dosage Form		u	Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle			000 capsules		
latex-free?		Yes				Product Sha	Capsule, Size 3		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No							Ampule					
correctional institution block?		Yes				Product Cold	r: Iron Grey	-	Glass		Minimum o	der quantity	?	Yes
opioid? Cannabinoid?		No	Country of Origin	US			TL 383		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dono for	No	Country of Origin	03		Product Imp	int:	-	Vial Liquid Sgl		If Yes how	many of whi	ch nackado	huno?
hospital scanning?	unit dose foi		Is this product covered u	inder the					Vial Powder Sql		12	Each	cii package	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (Yes			-	Vial Power Multi			Inner/Carton	/Pack	
								-	Other: Write In			Case		
·			FOR GENERIC DRUG PR	ODUCTS		•						4		
					Au	thorized Generic	*If Authorized Generic, other section fields are not applicable			IARMACY ORDER				
I. Orange Book Rating:	AB						section neids are not applicable	Rec. sell unit to		-		nit to pharma	acy:	
II. Generic Equivalent to What Bra	and?:	Hytrin®							e of 1000 capsules		X	Each		
			Y CHAIN SECURITY ACT (MATION			(Write-in, e.g. 1 HCPCS J-Code				Gram Milliliter		
		DRUG GUITE	CHAIN OLOONITT AOT					Tici Co 5-Code	•			winniter		
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes		GLN:	0359746000004			ITEM	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:	0359746				Dimensi	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product pure	hased	Item/Each:	0.66	3.4	3.4	7	80.92	1
to manufact a static measured strength					direct from m	fr?			0.00	0.4	0.4	· · ·	00.02	
Is product sold by manufacturer's			No										0.00	
Has FDA granted waiver/exception	n/exemption for pr						r repackaged product	Box/Carton/Bu	ndle/					
	n/exemption for pr		No				r repackaged product	Inner Pack:						12
Has FDA granted waiver/exception	n/exemption for pr	oduct?	No No	NFORMATION			r repackaged product		ndle/ 9.04	14	10.5	7.13	1048.11	
Has FDA granted waiver/exception	n/exemption for pr	oduct?	No	NFORMATION			r repackaged product	Inner Pack:		14	10.5	7.13		
Has FDA granted waiver/exception	n/exemption for pr	oduct?	No No	NFORMATION	Provide sour		r repackaged product	Inner Pack: Case:		14	10.5	7.13	1048.11 0	
Has FDA granted waiver/exception If yes, attach documentation from	n/exemption for pr m FDA. RFID tag(Y/N)	oduct?	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo		Inner Pack: Case:		14	10.5	7.13		
Has FDA granted waiver/exception If yes, attach documentation from	n/exemption for pr m FDA.	oduct? GTIN Saleable	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo		Inner Pack: Case:	9.04	14			0	
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pr m FDA. RFID tag(Y/N)	oduct? GTIN Saleable Quantity 1	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo N-14 59746383107		Inner Pack: Case:		14		7.13 WHOLESAL	0	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr m FDA. RFID tag(Y/N)	oduct? GTIN Saleable Quantity	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo N-14		Inner Pack: Case: Pallet:	9.04	14			0	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pr m FDA. RFID tag(Y/N)	oduct? GTIN Saleable Quantity 1	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo N-14 59746383107		Inner Pack: Case: Pallet: Regular Cost	9.04		Vendor #:	WHOLESALI	0	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr m FDA. RFID tag(Y/N)	oduct? GTIN Saleable Quantity 1	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo N-14 59746383107		Inner Pack: Case: Pallet:	9.04		Vendor #: Whsl. Code	WHOLESALI	0	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr m FDA. RFID tag(Y/N)	oduct? GTIN Saleable Quantity 1	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo N-14 59746383107		Inner Pack: Case: Pallet: Regular Cost Invoice Cost (W	9,04 COST INFORMATION		Vendor #:	WHOLESALI	0	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr m FDA. RFID tag(Y/N)	oduct? GTIN Saleable Quantity 1	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo N-14 59746383107		Inner Pack: Case: Pallet: Regular Cost	9.04		Vendor #: Whsl. Code	WHOLESALI	0	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr m FDA. RFID tag(Y/N)	Cuantity	No No N AND HIBCC PRODUCT I	NFORMATION	Provide sour	ce manufacturer fo N-14 59746383107		Inner Pack: Case: Pallet: Regular Cost Invoice Cost (W	9,04 COST INFORMATION		Vendor #: Whsl. Code	WHOLESALI	0	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr m FDA. RFID tag(Y/N)	Oduct? GTIN Saleable Quantity 1 1 12 0 0	No No No HIBCC PRODUCT II HIBCC		GTI 003 403	ce manufacturer fo N-14 59746383107 59746383105	Unit of Use GTIN-14	Inner Pack: Case: Pallet: Regular Cost Invoice Cost (W As of date:	9,04 COST INFORMATION VAC) (\$) 2/24/2025		Vendor #: Whsl. Code	WHOLESALI	0	Y:
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cartor/Bundle/Inner Pack X Case	n/exemption for pr m FDA. RFID tag(Y/N) N N I I I I I I I I	oduct? CGTIN Saleable Quantity 1 1 12 0 0	No No No HIBCC PRODUCT II HIBCC		GTI 003 403	ce manufacturer fo N-14 59746383107 59746383105 rd letter, PACKAGE		Inner Pack: Case: Pallet: Regular Cost Invoice Cost (M As of date:	9,04 COST INFORMATION VAC) (\$) 2/24/2025		Vendor #: Whsl. Code	WHOLESALI	0	Y:

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

Version 2024 For Design	ated Drop Ship Only Products, Please Use Page 3				
MATERIAL H	AZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? 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? Does the product label bear a CA Prop 65 warning? c. Contact Hazard? No C. Contact Hazard					
b. Proper Shipping Name c. DOT Hazard Class	Hazardous Waste Identification				
d. Packing Group					
e. Inhalation Hazard? No	EPA Hazardous Waste Code: Waste Characteristics				
Is this product regulated for shipment by IATA? (If yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS				
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:				
Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo	Med Guide Required No Limited Distribution Requirement No Comments / Details: (For example, iPledge program?)				
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);	REMS: 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 #:				
SP#	Registry:				
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments				
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS				
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: Is product returnable for credit:				
	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: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?				
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:				



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Version 2024 FC	OR DESIGNATED DROP SHIP PRODUCT ONLY - if	not a designated drop ship, do not complete.	
Order Method for Design	ated 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:	Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hour Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:	urs Days
Expedited Freight Charges or Otl	her Designated Drop Ship Fees:	Overnight and Priority Overnight	PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:		Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Priority Overnight receipt available:	Monday Tuesday Wednesday Thursday Friday
Class of Trade	- Restriction:	PO Receipt Cut off time:	
No restriction: Select YES if sold to retail pharmacy, he Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices onl Restricted from US territories? (explain in comments) Comments:	ospitals, clinics and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time:	ne #:
Other Data Information F	Required to Process PO:	Return Instruction	S
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product If so, which states? Other requirements? Comments?	ct in certain states?
Miscellaneo	bus Notes:		
		ADDITIONAL INFORMA Is product order for scheduled patient procedure? Is product order for restocking purposes?	