

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

Version 2024						Introduction Ty	/pe:			Final Version			Date:	2/24	/2025
			PRODUCT INFORMA	TION						SPECIAL HAN	NDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA						DA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	DA/BLA; PMA/510	(k): 075317				NDA 505(b) Type:	NOT APPLICA	BLE		erature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab										Ū					
DUNS:	118694141								Other	Temperature Range	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	me: Terazos	in HCI Capsules						(write in)					
Selling Unit NDC:	59746-384-10		Unit of Use NDC:				3-59746-384-10-4		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Terazosin Hydroch	nloride 2mg 1000ct Ca	apsules							product to be shippe product to be shippe				No No]
Active Ingredient(s):		Terazosin Hydrochlor	ride						b. Contact for tempe						1
URL for Additional Product Inform	nation.	www.cadista.com	n/products/full-product	t-lict					Name		lestions.	Customer S	ervice		
Address:	790 Township Line			<u></u>		Address 2:	Suite 325		Numb			(800) 313-4			
City:	Yardley				State:	PA	Zip: 19067			E-mail:		. ,	service@ca	dista.com	
Key Contact:	Customer Service				Email:	customer.servio	ce@cadista.com								
Phone Number:	(800) 313-4623				Fax:	N/A			c. Special regulation	s for product in any	states?			No]
Product Therapeutic Classification	n:	Benign Prostatic Hyp	pertrophy						Specia	al returns requiremen	ts for this product?			No	
	ADDITIO	ONAL PRODUCT INF	ORMATION			PRODUCT D	ESCRIPTION INFORM	ATION	d. Store product (un	it of sale) upright?				No	1
The use that is 0				Direct Chip () m lu c										1
The product is? a legend device?		N	Is the Product Is the Product	Direct-Ship C Neither	Jiny		1000 count		e. Shelf life:	ct product (unit of s	ale) from light?			No 24	Months
if yes, enter class #		No	Orphan Drug Status	Ineluter		Size:	1000 count			shelf life at launch ((if different).			24	Months
a product kit?		No	Orphan Drug Status				2mg		initia	Shell he at launch	(in university).				Wontins
if yes, list NDCs of		NO	FDA Approval Status			Strength:	2g				ORDER INFORM	ATION			
component parts						B	CAPSULE								
reverse numbered?		No				Dosage Form	:		Unit o	f Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X	Bottle		1 bottle of 1	000 capsules		
latex-free?		Yes				Product Shap	Capsule, Size 3			Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)	
preservative-free?		No				i roudet onup				Ampule					
correctional institution block?		Yes				Product Colo	r: Ivory			Glass		Minimum o	rder quantity	?	Yes
opioid?		No								Tube					
Cannabinoid?		No	Country of Origin	US		Product Impri	int: TL 384			Vial Liquid Sgl					_
If Unit Dose, is item bar coded to u	init dose for					-				Vial Liquid Multi			many of whi	ch package	type?
hospital scanning?			Is this product covered u Trade Agreements Act (Mar					Vial Powder Sql		12	Each	(D)-	
If Unit Dose, indicate NDC here:			I nade Agreements Act (174):	Yes					Vial Power Multi Other: Write In			Inner/Carton Case	/Раск	
				ODUCTO						Other. White in			Case		
			FOR GENERIC DRUG PR	ODUCIS											
					Au	uthorized Generic	*If Authorized Generic,	other		Pł	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not ap	pplicable	Rec. sell unit to cust	omer?		Ry hilling u	nit to pharma	acv:	
II. Generic Equivalent to What Bran		Hytrin®							1 bottle of 10			X	Each	acy.	
									(Write-in, e.g. 1 Vial)				Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	RMATION				HCPCS J-Code:				Milliliter		
				_									4		
Does supplier meet DSCSA definit	tion of manufactur	er?	Yes		GLN:	0359746000004				ITEN	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:	0359746				Weight Lbs.	Dimensi	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:										weight LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product purc	hased		Item/Each:	0.66	3.4	3.4	7	80.92	1
Is product sold by manufacturer's			No	_	direct from n						-	-			
Has FDA granted waiver/exception		oduct?	No		Provide sour	ce manufacturer for	repackaged product		Box/Carton/Bundle/					0.00	
If yes, attach documentation from	II FUA.								Inner Pack:						
		GTIN	AND HIBCC PRODUCT I	NFORMATION					Case:	9.04	14	10.5	7.13	1048.11	12
									Pallet:					-	
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GT	ΓIN-14						0	
	0, ,	Quantity								1	1				
X Item/Each	Ν	1			003	59746384104									
Box/Carton/Bundle/Inner Pack									CC	OST INFORMATION			WHOLESALI	ER USE ONL	Y:
X Case	N	12			403	59746384102									
Pallet									Regular Cost			Vendor #:			
									Invoice Cost (WAC)	(\$)	\$176.40	Whsl. Code			
										0/04/0605		Fineline Co	de:		
										2/24/2025					
									As of date:	2/2 1/2020					
									AS OF date.	2/2 1/2020					
		0													
*Please provide any additional info			Attach copy of SAFETY DA	ATA SHEET (SD	DS) or non haza		INSERT, LABEL AND P Designated Drop Ship			and BARCODE.					

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	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: Image: Contact Hazard Is the product a NIOSH hazardous drug? No If yes, indicate which: No					
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:					



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

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?	