

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

Version 2021						Introduction Ty	/pe: Post La	aunch Change		x Final Version			Date:	6/9/	/2023
			PRODUCT INFORMA	TION						SPECIAL H	ANDLING AND STO	RAGE REQU	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN				075	5317		'			Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica	ıble:														
DUNS:	022490515									Other Temperature Range	je Requirement				
Proprietary Name (If Applicable) a		ame: Ter	azosin HCl Capsules			una				(write in)					
Selling Unit NDC: UDI	59746-384-10		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-59746-384-10-4	4		Notes					
						WIVA Code.									
Description:	Terazosin Hydrod	chloride 2mg 1000c	ct Capsules							Is this product to be ship				No No	-
Active Ingredient(s):		Terazosin Hydro	chloride							Is this product to be ship	ped to customers on	dry ice?		INO	_
Active ingredient(s).		relazosiii riyalo	onionac						b. Contact for	r temperature excursion	auestions:				
URL for Additional Product Inform	mation:	www.cadista.	com/products/full-product	t-list					Name:			Customer S	Customer Service		
Address:	207 Kiley Drive					Address 2:				Number:		(800) 313-4			
City:	Salisbury				State:		<b>Zip</b> : 21801		Group E-mail: <u>customer.service@cadista.com</u>						
Key Contact:	(800) 313-4623	9			Email: Fax:	customer.servic	e@cadista.con	<u>n</u>	a Cuasial sas		1-12			Na	1
Phone Number: Product Therapeutic Classification		Benign Prostatic	Llynortrophy		rax:	IN/A			c. Special reg	julations for product in a Special returns requirem	-			No No	-
Product Therapeutic Classification	on:	Berlight Flosialic	пуренторну							Special returns requirer	ents for this product	ſ		INO	
	ADDIT	IONAL PRODUCT	INFORMATION			PRODUCT D	ESCRIPTION INF	ORMATION	d Store prod	uct (unit of sale) upright	,			No	1
The product is?			Is the Product	Direct-Ship C	inly				a. ototo p. oa	Protect product (unit o				No	1
a legend device?		No	Is the Product	Neither	Tilly		1000 coun	nt	e. Shelf life:	Protect product (unit o	sale) from light?			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	1000 00011	ıt	c. Onen me.	Initial shelf life at laund	h (if different):				Months
a product kit?		No				Ctuan mth.	2mg				(				
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFOR	MATION			
component parts						Dosage Form:	CAPSULE								
reverse numbered?		No	All B							Unit of Sale			NDC selling		
co-licensed?		No Yes	Allergens Present				Capsule, S	Sizo 3		X Bottle Box/Carton			000 capsules .g. 1 Box of 1		
preservative-free?		No				Product Shap	e: Capsule, C	Size S		Ampule		(vviite-iii, e	.g. 1 Dox 01 1	O viais)	
correctional institution block?		Yes				Book to a Color	Ivory			Glass		Minimum o	rder quantity	y?	Yes
opioid?		No				Product Color	r:   '			Tube					
Cannabinoid?		No	Country of Origin	US		Product Impri	nt: TL 384			Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					. roudot impir				Vial Liquid Mul				ich package	type?
hospital scanning?			Is this product covered u Trade Agreements Act (		Vaa					Vial Powder So		12	Each	-/Deals	
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)!	Yes					Vial Power Mu Other: Write In	u		Inner/Cartor	1/Pack	
			FOR GENERIC DRUG PR	ODUCTS						Other: Write III			Ousc		
			1011 021121110 01100111	0200.0											
					Au	thorized Generic	*If Authorized Ger	neric, other			PHARMACY ORDE	R / BILL UNIT			
I. Orange Book Rating: AB					section fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:				
II. Generic Equivalent to What Brand?: Hytrin®						1 bottle of 1000 capsules			X Each						
-									(Write-in, e.g.	1 Vial)	_		Gram		
		DRUG SUF	PPLY CHAIN SECURITY ACT (	DSCSA) INFOR	MATION								Milliliter		
Dans sumplier most DSCSA defin		2	Von	_	CLN.	0359746000004				17	EM AND PACKING	INFORMATIO	M		
Does supplier meet DSCSA defining product exempt from DSCSA?		rerr	Yes No	-	GLN:	0359746000004				''	EW AND FACKING	INFORMATIC	IN .		
· ·					GCP:	0359746					Dimen	sions (US ms	mte \	Valuma	Calaabla #
If yes, select exemption: Other exemption - Write in:					GCP:	0359746				Weight Lbs	. Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If ves. was or	riginal product purch	hased		Item/Each:					_ ` _ <i></i>	
Is product sold by manufacturer's	s exclusive distribi	utor?	No		direct from m					0.66	3.5	3.5	6.4	78.40	1
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer for	repackaged prod	duct	Box/Carton/B	Sundle/				0.00	
If yes, attach documentation fro	om FDA.								Inner Pack:					0.00	
			GTIN AND HIBCC PRODUCT I	VEODMATION					Case:	8.53	14.25	10.75	7	1072.31	12
			TIN AND HIBCC PRODUCT II	NFORMATION					Pallet:						
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTI	N-14	Unit of U	Ise GTIN-14	r anet.					0.00	
X Item/Each		1				59746384104									
Box/Carton/Bundle/Inner Pack						COST INFORMATION				WHOLESALER USE ONLY:					
X Case		12			403	59746384102									
Pallet									Regular Cost	(14/4-0) (6)		Vendor #:			
	_								Invoice Cost	(VVAC) (\$)	\$176.4	0 Whsl. Code Fineline Co			
111									11			- Fineline Co	rue.		
									As of date:						
									As of date:			-			
									As of date:						
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza	ird letter, PACKAGE I	NSERT, LABEL A	AND PHOTO OF F		AGING and BARCODE.					



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

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):								
a. Cytotoxic?	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
Is the product a CA Prop 65 carcinogen?  No	Organic Corrosive Inorganic Oxidizer							
Is the product a CA Prop 65 reproductive toxicant?  Does the product label bear a CA Prop 65 warning?  No	Inorganic Oxidizer Steroid/Androgen Contact Hazard							
boes the product label bear a OATTOP to warning:	Ornaci Tazard							
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No							
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:							
(If yes, attach SDS with special instructions.)	NFPA Storage Level:							
e. Does the product contain DEHP?								
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?							
(if yes, answer a-e below and provide SDS)	If yes, indicate which:							
a. UN/Identification Number b. Proper Shipping Name								
c. DOT Hazard Class	Hazardous Waste Identification							
d. Packing Group								
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics							
Is this product regulated for shipment by IATA?								
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS							
a. UN/Identification Number								
b. Proper Shipping Name	Is there a REMS on this product?							
c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry?  Website URL:							
e. Inhalation Hazard?	Website ORL.							
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? No	REMS:							
RQ Threshold:	REMS Program Manager Name: Phone:							
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:							
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:							
No (if yes, identify method below)  Limited Quantity	Provider Name: DEA #: Site Enrollment Number assigned NCPDP#:							
Consumer Commodity, ORM-D	by Supplier: NPI #:							
Small Quantity (49 CFR 173.4)								
Special Permit; DOT-SP	Comments							
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#	Registry:							
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:							
	Comments							
Is the Product Controlled Substance 2	RETURN INSTRUCTIONS							
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	KETORI NOTIONS							
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:	Consider outletions or returns continued for this							
Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states?							
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?							
Comments:								
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:							
- INIGCLELAT								



## **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 fo	r Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt:
F	Name: Phone:	Ships regular ground for 3-10 days receipt:
Expedited Freight Charg	ges 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:		PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available:  PO Receipt Cut off time: Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Infor	rmation Required to Process PO:	Return Instructions
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 in certain states?  If so, which states? Other requirements? Comments?
Mis	scellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?