

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

						Introduction Type:			Final Version			Date:	2/24/2	2025
			PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Jubila	ant Cadista Pharma	aceuticals Inc.				Application:	ANDA	a. Temperature – Indica	ate the USP tempe	rature range for th	is product.			
Application Number for NDA/ANDA/BL		075317				NDA 505(b) Type:	NOT APPLICABLE		ture Range	Controlled Room -		and 25 C (68°	' – 77° F)	
Medical Device Class, if applicable:														
	94141							Other Ter	mperature Range F	Requirement				
Proprietary Name (If Applicable) and Est		Terazos	in HCl Capsules						ite in)					
	6-385-10		Unit of Use NDC:			UPC: 3-59	9746-385-10-1	Notes						
UDI			CVX Code:			MVX Code:								
Description: Terazosin Hydrochloride 5mg 1000ct Capsules								lo this pro	aduat to be abinned	I to customers on ic	-02	-	No	
Terazosii nyurounionide sing rootot capsues										to customers on d		l	No	
Active Ingredient(s): Terazosin Hydrochloride							- Is an pro	oddot to bo omppoo	to odotomoro on d	.,	Į.			
							b. Contact for temperat	ure excursion que	estions:					
URL for Additional Product Information: www.cadista.com/products/full-product-list				t-list				Name:	•		Customer Se	ervice		
Address: 790 T	Township Line Road	ship Line Road			Address 2: Suite 325			Number:			(800) 313-46	23		
City: Yardi	,	s				PA Zip	Group E-	-mail:		customer.	service@ca	dista.com		
.,					Email:	customer.service@								
) 313-4623				Fax:	N/A		c. Special regulations f				l	No	
Product Therapeutic Classification:	Benig	gn Prostatic Hyp	ertrophy					Special re	eturns requirement	s for this product?			No	
	. DDITION .													
	ADDITIONAL	PRODUCT INFO	DRMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit o	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly			Protect p	product (unit of sa	le) from light?		Į.	No	
a legend device?	No		Is the Product	Neither		Size:	1000 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status				_	Initial sh	elf life at launch (i	f different):				Months
a product kit?	No					Strength:	5mg			ODDED INCODE	ATION			
if yes, list NDCs of component parts			FDA Approval Status				CAPSULE			ORDER INFORM	ATION			
reverse numbered?	No					Dosage Form:	CAPSOLE	Unit of S	alo		What is the	NDC selling	unit?	
co-licensed?	No		Allergens Present						Bottle		1 bottle of 10			
latex-free?	Yes		Anergens i resent				Capsule, Size 3		Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?	No					Product Shape:			Ampule		,,	,	,	
correctional institution block?	Yes					Draduet Cales	Orange		Glass		Minimum or	der quantity	?	Yes
opioid?	No					Product Color:			Tube					
Cannabinoid?	No		Country of Origin	US		Product Imprint:	TL 385		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unit dos	se for					1 Todaot III.priitti			Vial Liquid Multi			many of which	th package t	ype?
hospital scanning?			Is this product covered u						Vial Powder Sql		12	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	IAA)?	Yes				Vial Power Multi			Inner/Carton/	Pack	
<u> </u>									Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCIS										
					A.,	harinad Canaria *If A	uthorized Coperia other		DLI	APMACY OPDER	/ BILL LINIT			
	Authorized Generic "If Authorized Generic, other					tion fields are not applicable	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB				coolion notae are not applicable			Rec. sell unit to custom		1		nit to pharma	cy:		
II. Generic Equivalent to What Brand?: Hytrin®								1 bottle of 1000	capsules		X	Each Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	MATION			(Write-in, e.g. 1 Vial) HCPCS J-Code:				Milliliter		
		51.00 00. 1 21	010 010 010 (,5000,1,				1101 00 0 00ac.		1		, iviiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii		
Does supplier meet DSCSA definition of														
	manufacturer?		Yes		GLN:	0359746000004			ITEM	AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?	f manufacturer?		Yes No	_	GLN:	0359746000004			ITEM	AND PACKING IN	IFORMATION	N		
Is product exempt from DSCSA?	f manufacturer?												Volume	Saleable #
Is product exempt from DSCSA? If yes, select exemption:	f manufacturer?				GLN: GCP:	0359746000004			ITEM	Dimensio	ons (US msm	nts.)	Volume (Cube)	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	f manufacturer?				GCP:	0359746	ed	Item/Each:	Weight Lbs.	Dimensio Depth	ons (US msm Width	nts.) Height	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption:			No		GCP:	0359746 ginal product purchase	ed	Item/Each:		Dimensio	ons (US msm	nts.)		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	sive distributor?	?	No No		GCP: If yes, was ori	0359746 ginal product purchase		Item/Each: Box/Carton/Bundle/	Weight Lbs.	Dimensio Depth	ons (US msm Width	nts.) Height	(Cube) 80.92	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclu	sive distributor?	?	No No		GCP: If yes, was ori	0359746 ginal product purchase r?			Weight Lbs.	Dimensio Depth	ons (US msm Width	nts.) Height	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclu Has FDA granted waiver/exception/exen	sive distributor?		No No No No		GCP: If yes, was ori	0359746 ginal product purchase r?		Box/Carton/Bundle/	Weight Lbs.	Dimension Depth 3.4	ons (US msm Width 3.4	Height	(Cube) 80.92 0.00	Pieces 1
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclu Has FDA granted waiver/exception/exen If yes, attach documentation from FDA Saleable Unit of Measure RF	isive distributor? inption for product FID tag(Y/N) Sales Quar	GTIN able ntity	No No No No No		GCP: If yes, was oridirect from mf Provide source GTIN	0359746 ginal product purchaser? e manufacturer for rep	ackaged product	Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs.	Dimension Depth 3.4	ons (US msm Width 3.4	Height	80.92 0.00 1048.11	Pieces 1
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclu Has FDA granted waiver/exception/exen If yes, attach documentation from FDA Saleable Unit of Measure RF X Item/Each Box/Cartor/Bundle/Inner Pack	isive distributor? inption for product i. FID tag(Y/N) Salea Quar	GTIN able ntity	No No No No No		GCP: If yes, was oridirect from mf Provide source GTIN 0035	0359746 ginal product purchaser? e manufacturer for rep	ackaged product	Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs.	Dimension Depth 3.4	ons (US msm Width 3.4	Height	(Cube) 80.92 0.00 1048.11	1 12
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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): SDS Hazard Classification a. Cytotoxic? No 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? Oxidizer No Inorganic 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 No 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



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

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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: 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: 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?				