

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

						Introduction Type:			Final Version			Date:		/2025
			PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Jub	bilant Cadista PI	narmaceuticals Inc.				Application:	ANDA	a. Temperature – Indica	ate the USP tempe	rature range for th	is product.			
Application Number for NDA/ANDA/E						NDA 505(b) Type:	NOT APPLICABLE		ture Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:	,	,						1						
	8694141							Other Ter	mperature Range F	Requirement				
Proprietary Name (If Applicable) and E		ne: Terazos	sin HCl Capsules						ite in)					
	746-384-06		Unit of Use NDC:			UPC: 3-59	746-384-06-7	Notes						
UDI			CVX Code:			MVX Code:								
Description: Terazosin Hydrochloride 2mg 100ct Capsulles								lo this pro	aduat to be abinned	to customers on ic	2		No	1
relazosin nyurocilionoe zing rouci capsules										to customers on di			No	
Active Ingredient(s): Terazosin Hydrochloride							- I io allo più	oddot to bo omppoo	to odotomoro on di	, 100.		110	J	
						b. Contact for temperat	ure excursion que	estions:						
URL for Additional Product Information	on:	www.cadista.com	n/products/full-product	-list				Name:	•		Customer Se	rvice		
Address: 790	0 Township Line	Road				Address 2: Suit	e 325	Number:			(800) 313-46	23		
	ardley	State: PA					19067	Group E-mail: <u>customer.service@cadista.com</u>						
	ustomer Service				Email:	customer.service@								
1.0	00) 313-4623				Fax:	N/A		c. Special regulations f					No	
Product Therapeutic Classification:		Benign Prostatic Hyp	pertrophy					Special re	eturns requirements	s for this product?			No	
								.						1
	ADDITIC	NAL PRODUCT INF	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit o	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly			Protect p	product (unit of sa	le) from light?			No	]
a legend device?		No	Is the Product	Neither		Size:	100 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			OILC.		Initial sh	elf life at launch (i	f different):				Months
a product kit?		No				Strength:	2mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	ATION			
component parts						Dosage Form:	CAPSULE				140	NDO III		
reverse numbered? co-licensed?		No	All B					Unit of S	Bottle		What is the 1 bottle of 10		unitr	
latex-free?		No	Allergens Present				Capsule, Size 3		Box/Carton			g. 1 Box of 10	) \/iolo\	
preservative-free?		Yes No				Product Shape:	Capsule, Size 3		Ampule		(write-iii, e.	g. 1 BOX 01 10	) viais)	
correctional institution block?		Yes					Ivory		Glass		Minimum or	der quantity	2	Yes
opioid?		No				Product Color:	ivory		Tube		······································	acı quantity		103
Cannabinoid?		No	Country of Origin	US			TL 384		Vial Liquid Sql					
If Unit Dose, is item bar coded to unit d			,			Product Imprint:			Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?
hospital scanning?			Is this product covered up	nder the					Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:		-	Trade Agreements Act (T	AA)?	Yes				Vial Power Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS										
			FOR GENERIC DRUG PRO	ODUCTS										
			FOR GENERIC DRUG PRO	ODUCTS	Aut		uthorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating: AB	3		FOR GENERIC DRUG PRO	ODUCTS	Aut		authorized Generic, other ion fields are not applicable	Rec. sell unit to custom		ARMACY ORDER	/ BILL UNIT Rx billing u	nit to pharma	cy:	
I. Orange Book Rating:  AB II. Generic Equivalent to What Brand?:		Hytrin®	FOR GENERIC DRUG PRO	ODUCTS	Aut			Rec. sell unit to custom 1 bottle of 100	ner?	ARMACY ORDER		nit to pharma Each	ıcy:	
								1 bottle of 100 (Write-in, e.g. 1 Vial)	ner?	ARMACY ORDER	Rx billing u	Each Gram	ncy:	
			FOR GENERIC DRUG PRO					1 bottle of 100	ner?	ARMACY ORDER	Rx billing u	Each	ıcy:	
II. Generic Equivalent to What Brand?:	<b>'</b> :	DRUG SUPPLY	Y CHAIN SECURITY ACT (	DSCSA) INFOR	MATION	sec		1 bottle of 100 (Write-in, e.g. 1 Vial)	ner? capsules		Rx billing u	Each Gram Milliliter	ıcy:	
II. Generic Equivalent to What Brand?:  Does supplier meet DSCSA definition	<b>'</b> :	DRUG SUPPLY	Y CHAIN SECURITY ACT (I	DSCSA) INFOR				1 bottle of 100 (Write-in, e.g. 1 Vial)	ner? capsules	ARMACY ORDER	Rx billing u	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Brand?:  Does supplier meet DSCSA definition Is product exempt from DSCSA?	<b>'</b> :	DRUG SUPPLY	Y CHAIN SECURITY ACT (	DSCSA) INFOR	MATION GLN:	0359746000004		1 bottle of 100 (Write-in, e.g. 1 Vial)	ner? capsules	AND PACKING IN	Rx billing un X	Each Gram Milliliter		
II. Generic Equivalent to What Brand?:  Does supplier meet DSCSA definition Is product exempt from DSCSA? If yes, select exemption:	<b>'</b> :	DRUG SUPPLY	Y CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION	sec		1 bottle of 100 (Write-in, e.g. 1 Vial)	ner? capsules	AND PACKING IN	Rx billing un X FORMATION	Each Gram Milliliter	Volume	Saleable #
II. Generic Equivalent to What Brand?:  Does supplier meet DSCSA definition is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in:	<b>'</b> :	DRUG SUPPLY	Y CHAIN SECURITY ACT (I Yes No	DSCSA) INFOR	MATION GLN: GCP:	0359746000004 0359746	ion fields are not applicable	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code:	ner? capsules ITEM	AND PACKING IN	Rx billing un X	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Brand?:  Does supplier meet DSCSA definition is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged?	of manufacture	DRUG SUPPLY	Y CHAIN SECURITY ACT (I Yes No	DSCSA) INFOR	GLN: GCP: If yes, was ori	0359746000004 0359746	ion fields are not applicable	1 bottle of 100 (Write-in, e.g. 1 Vial)	ner? capsules ITEM	AND PACKING IN	Rx billing un X FORMATION	Each Gram Milliliter	Volume	
II. Generic Equivalent to What Brand?:  Does supplier meet DSCSA definition is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exci	of manufacture	DRUG SUPPLY	Y CHAIN SECURITY ACT (  Yes  No  No  No	DSCSA) INFOR	MATION GLN: GCP: If yes, was ordirect from m	0359746000004 0359746 0359746 lginal product purchase	ion fields are not applicable	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code:	ner? capsules ITEM Weight Lbs.	AND PACKING IN Dimensic Depth	Rx billing un X  FORMATION Ons (US msm Width	Each Gram Milliliter  ts.) Height	Volume (Cube)	Pieces
II. Generic Equivalent to What Brand?:  Does supplier meet DSCSA definition Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exc	of manufacture	DRUG SUPPLY	Y CHAIN SECURITY ACT (I Yes No	DSCSA) INFOR	MATION GLN: GCP: If yes, was ordirect from m	0359746000004 0359746	ion fields are not applicable	1 bottle of 100 (Write-in, e.g. 1 Vial) HCPCS J-Code:  Item/Each: Box/Carton/Bundle/	ner? capsules ITEM Weight Lbs.	AND PACKING IN Dimensic Depth	Rx billing un X  FORMATION Ons (US msm Width	Each Gram Milliliter  ts.) Height	Volume (Cube)	Pieces
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## Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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?					