

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

					Introduction Type	: Post Launch Change		x Final Version			Date:	7/12/	2021					
		PRODUCT INFORM	ATION					SPECIAL HANI	DLING AND STOR	AGE REQUIF	EMENTS*							
Company Name:	a. Temperature – Indicate the USP temperature range for this product.																	
Application Number for NDA/AN	Jubilant Cadista Pharmaceutic IDA/BLA (drug); PMA/510(k)(maximum)		075	317	Application	ANDA		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)						
Medical Device Class, if applical		•						, ,										
DUNS:	022490515							Other Temperature Range F	Requirement									
Proprietary Name (If Applicable) a	and Established Name:	Terazosin HCl Capsules						(write in)										
Selling Unit NDC:	59746-385-10	Unit of Use NDO	:		UPC: 3-9	9746-385-10-1		Notes										
UDI		CVX Code:			MVX Code:													
Description:	Terazosin Hydrochloride 5mg	1000ct Capsulles						Is this product to be shipped	to customers on i	e?		No						
	,							Is this product to be shipped				No						
Active Ingredient(s):	Terazosin H																	
	b. Contact for temperature excursion questions:																	
URL for Additional Product Inform		lista.com/products/full-produ	<u>ict-list</u>					Name:		Customer Se								
Address:	207 Kiley Drive				Address 2:			Number:		(800) 313-46								
City:	Salisbury	•				ip: 21801	Group E-mail: customer.service@cadista.com											
Key Contact:	Jackie Emershaw (410) 912-3722			Email: Fax:	Jackie.Emershaw((215) - 443 - 9646	<u> pjubl.com</u>			-1-10			NI.						
Phone Number:		atada tha agrando.		гах.	(215) - 443 - 9646		c. Special reg	ulations for product in any				No						
Product Therapeutic Classificatio	n: Benign Pro	static Hypertrophy						Special returns requirement	s for this product?			No						
	ADDITIONAL DROP	NIOT INFORMATION			PROPUST DES	CRIPTION INFORMATION												
	ADDITIONAL PROD	OUCT INFORMATION			PRODUCT DES	CRIPTION INFORMATION	a. Store produ	uct (unit of sale) upright?				No						
The product is?		Is the Product	Direct-Ship C	inly				Protect product (unit of sa	le) from light?			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 shelf life at launch (i	f different):				Months					
a product kit?	No	FD4 4			Strength:	5mg			ORDER INFORM	ATION								
if yes, list NDCs of component parts		FDA Approval Status				CAPSULE			ORDER INFORM	ATION								
reverse numbered?	No				Dosage Form:	CAPSULE		Unit of Sale		What is the	NDC selling	unit?						
co-licensed?	No	Allergens Present						X Bottle		1 bottle of 10		unit.	ſ					
latex-free?	Yes	Allergens Fresent				Capsule, Size 3		Box/Carton		(Write-in, e.) Vials)						
preservative-free?	No				Product Shape:			Ampule		(,	,						
correctional institution block?	Yes				Decident Online	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 u	unit dose for				r roduct imprint			Vial Liquid Multi			many of whi	ch package t	type?					
hospital scanning?		Is this product covered						Vial Powder Sql		12	Each							
If Unit Dose, indicate NDC here:		Trade Agreements Act	(TAA)?	Yes				Vial Power Multi			Inner/Carton	Pack						
							<u> </u>	Other: Write In			Case							
		FOR GENERIC DRUG P	RODUCTS															
								DU	ADMACY ORDER	/ DILL LINET	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:				Au		Authorized Generic, other			ARMACY ORDER				Rec. sell unit to customer? Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: Hytrin				AU		Authorized Generic, other ction fields are not applicable		to customer?	ARMACY ORDER	Rx billing u		ісу:						
II. Generic Equivalent to What Bra	AB Hytrin			AU			1 bott	to customer? tle of 1000 capsules	ARMACY ORDER		Each	icy:						
II. Generic Equivalent to What Bra	and?: Hytrin	SUDDI V CHAIN SECUDITY ACT	(Decea) INFOR	<u> </u>				to customer? tle of 1000 capsules	ARMACY ORDER	Rx billing u	Each Gram	ісу:						
II. Generic Equivalent to What Bra	and?: Hytrin	SUPPLY CHAIN SECURITY ACT	(DSCSA) INFOR	<u> </u>			1 bott	to customer? tle of 1000 capsules	ARMACY ORDER	Rx billing u	Each	icy:						
	nd?: Hytrin		(DSCSA) INFOR	MATION	se		1 bott	to customer? die of 1000 capsules 1 Vial)		Rx billing u	Each Gram Milliliter	асу:						
Does supplier meet DSCSA defini	nd?: Hytrin	SUPPLY CHAIN SECURITY ACT Yes No	(DSCSA) INFOR	<u> </u>			1 bott	to customer? die of 1000 capsules 1 Vial)	ARMACY ORDER	Rx billing u	Each Gram Milliliter	acy:						
Does supplier meet DSCSA defini	nd?: Hytrin	Yes	(DSCSA) INFOR	MATION GLN:	0359746000004		1 bott	to customer? die of 1000 capsules 1 Vial)	AND PACKING I	Rx billing un X	Each Gram Milliliter		Salashia #					
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	nd?: Hytrin	Yes	(DSCSA) INFOR	MATION	se		1 bott	to customer? die of 1000 capsules 1 Vial)	AND PACKING IN	Rx billing un X IFORMATION ons (US msm	Each Gram Milliliter	Volume	Saleable #					
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?: Hytrin	Yes No		MATION GLN: GCP:	0359746000004 0359746		1 bott (Write-in, e.g.	to customer? tle of 1000 capsules 1 Vial) ITEM Weight Lbs.	AND PACKING IN Dimensi Depth	Rx billing un X IFORMATION DOES (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces					
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	DRUG	Yes		MATION GLN: GCP: If yes, was or	0359746000004		1 bott	to customer? tle of 1000 capsules 1 Vial)	AND PACKING IN	Rx billing un X IFORMATION ons (US msm	Each Gram Milliliter	Volume						
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	DRUG	Yes No		MATION GLN: GCP: If yes, was or purchased di	0359746000004 0359746 riginal product frect from mfr?	ction fields are not applicable	1 bott (Write-in, e.g.	to customer? tle of 1000 capsules 1 Vial) ITEM Weight Lbs. 0.66	AND PACKING IN Dimensi Depth	Rx billing un X IFORMATION DOES (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces					
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	DRUG ition of manufacturer? s exclusive distributor?	Yes No No		MATION GLN: GCP: If yes, was or purchased di	0359746000004 0359746	ction fields are not applicable	1 bott (Write-in, e.g.	to customer? tle of 1000 capsules 1 Vial) ITEM Weight Lbs. 0.66	AND PACKING IN Dimensi Depth	Rx billing un X IFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces					
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	DRUG ition of manufacturer? s exclusive distributor?	No No No No No		MATION GLN: GCP: If yes, was or purchased di	0359746000004 0359746 riginal product frect from mfr?	ction fields are not applicable	1 bott (Write-in, e.g. Item/Each: Box/Carton/B	to customer? tle of 1000 capsules 1 Vial) ITEM Weight Lbs. 0.66 undle/	AND PACKING IN Dimensi Depth 3.5	Rx billing us X IFORMATION Ons (US msm Width 3.5	Each Gram Milliliter ts.) Height 6.3	Volume (Cube) 77.18	Pieces 1					
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	DRUG ition of manufacturer? s exclusive distributor?	Yes No No		MATION GLN: GCP: If yes, was or purchased di	0359746000004 0359746 riginal product frect from mfr?	ction fields are not applicable	1 bott (Write-in, e.g. Item/Each: Box/Carton/B Inner Pack:	to customer? tle of 1000 capsules 1 Vial) ITEM Weight Lbs. 0.66	AND PACKING IN Dimensi Depth	Rx billing un X IFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces					
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Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X	DRUG ition of manufacturer? s exclusive distributor? n/exemption for product? m FDA. Saleable Qual	No No No No ONO OTIN AND HIBCC PRODUCT		MATION GLN: GCP: If yes, was or purchased di Provide sour	0359746000004 0359746 0359746 riginal product irect from mfr? cc manufacturer for re	packaged product	Item/Each: Box/Carton/B Inner Pack: Case:	to customer? tle of 1000 capsules 1 Vial) ITEM Weight Lbs. 0.66 undle/	AND PACKING IN Dimensi Depth 3.5	Rx billing un X IFORMATION Ons (US msm Width 3.5	Each Gram Milliliter ts.) Height 6.3	Volume (Cube) 77.18 0.00	Pieces 1 12					
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Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X	DRUG ition of manufacturer? s exclusive distributor? n/exemption for product? m FDA. Saleable Qual	No No No No ONO OTIN AND HIBCC PRODUCT		MATION GLN: GCP: If yes, was or purchased di Provide sour	0359746000004 0359746 0359746 riginal product irect from mfr? cc manufacturer for re	packaged product	Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	to customer? tle of 1000 capsules 1 Vial) Weight Lbs. 0.66 undle/ 8.53 COST INFORMATION	Dimensi Depth 3.5	Rx billing un X FORMATION ons (US msm Width 3.5 10.75 Vendor #: Whsl. Code	Each Gram Milliliter ts.) Height 6.3 7	Volume (Cube) 77.18 0.00 1072.31 0.00	Pieces 1 12					
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Version 2021

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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): a. Cytotoxic? No SDS Hazard Classification 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? No Inorganic Oxidizer 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 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)

Version 2021

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:	Overnight receipt available:					
Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	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?					