

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

					Introduction Type:							2/24/	
		PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STORA	AGE REQUIF	EMENTS*		
Company Name: Jubilant Cad	ista Pharmaceuticals I	nc.			Application:	ANDA	a. Temperature – Indica	ate the USP tempe	rature range for th	is product.			
Application Number for NDA/ANDA/BLA; PM		5317			NDA 505(b) Type:	NOT APPLICABLE		ture Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:	,												
DUNS: 118694141							Other Ter	mperature Range R	equirement				
Proprietary Name (If Applicable) and Establish	ed Name: Te	razosin HCI Capsules						te in)					
Selling Unit NDC: 59746-385-		Unit of Use NDC:			UPC: 3-59	746-385-06-4	Notes						
UDI		CVX Code:			MVX Code:								
Description: Terazosin Hydrochloride 5mg 100ct Capsulles								aduat to be objected	to customers on ic	0.2		No	1
Description: Telazosin hydrocinonoe sing rood capsules									to customers on dr			No	
Active Ingredient(s): Terazosin Hydrochloride						- Is also pic	oddot to bo omppod	to oddiomoro on di	, 100.			l	
						b. Contact for temperat	ure excursion que	stions:					
URL for Additional Product Information:	www.cadista	.com/products/full-product-	:-list				Name:	•		Customer Se	rvice		
Address: 790 Townsh	p Line Road				Address 2: Suite	325	Number:			(800) 313-46	23		
City: Yardley	State: PA Zip: 19067						Group E-	-mail:		customer.s	ervice@ca	dista.com	
Phone Number: (800) 313-4				Fax:	N/A		c. Special regulations f	-				No	
Product Therapeutic Classification:	Benign Prostation	c Hypertrophy					Special re	eturns requirements	s for this product?			No	
A	DITIONAL PRODUCT	T INFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit o	f sale) upright?				No	
The product is?		Is the Product	Direct-Ship On	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:	5mg							
if yes, list NDCs of		FDA Approval Status			J				ORDER INFORM	ATION			
component parts	1				Dosage Form:	CAPSULE				140	UDO III'		
reverse numbered? co-licensed?	No	All B					Unit of S	ale Bottle		What is the 1 bottle of 10		unit?	
latex-free?	No	Allergens Present				Capsule, Size 3		Box/Carton			o capsules a. 1 Box of 10) Viole)	
preservative-free?	Yes No				Product Shape:	Capsule, Size 3		Ampule		(vviite-iii, e.	j. 1 DOX 01 10	, viais)	
correctional institution block?	Yes					Orange		Glass		Minimum or	der quantity	2	Yes
opioid?	No				Product Color:	Orange		Tube		······································	aci qualitity		103
Cannabinoid?	No	Country of Origin	US			TL 385		Vial Liquid Sql					
If Unit Dose, is item bar coded to unit dose for		, , , , ,			Product Imprint:			Vial Liquid Multi		If Yes, how	nany of which	ch package t	type?
hospital scanning?		Is this product covered ur	nder the					Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (T.	ΓAA)?	Yes				Vial Power Multi			Inner/Carton	/Pack	
				103							IIIII CI/ Cartori	ii doit	
			L	103				Other: Write In			Case	,, don	
		FOR GENERIC DRUG PRO		103								n don	
		FOR GENERIC DRUG PRO						Other: Write In				, don	
		FOR GENERIC DRUG PRO				uthorized Generic, other		Other: Write In	ARMACY ORDER			, uoix	
I. Orange Book Rating: AB		FOR GENERIC DRUG PRO				uthorized Generic, other on fields are not applicable		Other: Write In			Case		
I. Orange Book Rating: II. Generic Equivalent to What Brand?:	Hytrin®	FOR GENERIC DRUG PRO						Other: Write In PH. ner?		/ BILL UNIT	Case		
	-		ODUCTS	Aut			Rec. sell unit to custom 1 bottle of 100 (Write-in, e.g. 1 Vial)	Other: Write In PH. ner?		/ BILL UNIT Rx billing ur	Case lit to pharma Each Gram		
	-	FOR GENERIC DRUG PRO	ODUCTS	Aut			Rec. sell unit to custom 1 bottle of 100	Other: Write In PH. ner?		/ BILL UNIT Rx billing ur	Case iit to pharma Each		
II. Generic Equivalent to What Brand?:	DRUG SU	PPLY CHAIN SECURITY ACT (E	ODUCTS DSCSA) INFORM	Aut	sect		Rec. sell unit to custom 1 bottle of 100 (Write-in, e.g. 1 Vial)	Other: Write In PH. ter? capsules		/ BILL UNIT Rx billing ur X	Case iit to pharma Each Gram Milliliter		
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of manu	DRUG SU	PPLY CHAIN SECURITY ACT (E Yes	ODUCTS DSCSA) INFORM	Aut			Rec. sell unit to custom 1 bottle of 100 (Write-in, e.g. 1 Vial)	Other: Write In PH. ter? capsules		/ BILL UNIT Rx billing ur X	Case iit to pharma Each Gram Milliliter		
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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)

Version 2024

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?					