

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

						Introduction Ty	pe: Post Launch Change		x Final Version			Date:	7/12/	/2021
			PRODUCT INFORMAT	TION					SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Jubilant Cadista Ph	narmaceuticals Inc.				Application	n: ANDA	a. Temperature	- Indicate the USP temper	ature range for th	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 2096						74000000	7.11.571			Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical		, , , , , , , , , , , , , , , , , , , ,	-					•	omporataro rtango					
DUNS:	022490515								Other Temperature Range Ro	equirement				
Proprietary Name (If Applicable) a		me: Tizanio	line HCI Capsules						(write in)					
Selling Unit NDC:	59746-671-34		Unit of Use NDC:			UPC: 3	3-59746-671-34-1	- N	lotes					
UDI			CVX Code:			MVX Code:								
Description:	Tizanidina Hydroch	nloride 4mg 150ct Ta	blote					-	s this product to be shipped	to quetomore en ie	202		No	1
Description.	rizariidirie riyuroci	lionae 4mg 150ct ra	Diets						this product to be shipped				No	-
Active Ingredient(s):		Tizanidine Hydrochl	oride						tina product to be ampped	to customers on a	ii y 100 :		140	-1
riouro iligi outoria(o).								b. Contact for te	emperature excursion que	stions:				
URL for Additional Product Inform	mation:	www.cadista.cor	n/products/full-product	t-list					lame:		Customer Se	ervice		
Address:	207 Kiley Drive		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			Address 2:			lumber:		(800) 313-46			
City:	Salisbury				State:	MD	Zip: 21801	G	roup E-mail:		customer.	service@ca	adista.com	
Key Contact:	Jackie Emershaw					Jackie.Emershav	v@jubl.com							
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646		c. Special regul	ations for product in any s	tates?			No	
Product Therapeutic Classificatio	on:	Muscle Relaxant						S	pecial returns requirements	for this product?			No	
	'				_									-
	ADDITIO	NAL PRODUCT INF	ORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only			П р	rotect product (unit of sale	e) from light?			No	1
a legend device?		No	Is the Product	Neither	-		150 count	e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			Size:		Ir	nitial shelf life at launch (if	different):				Months
a product kit?		No	. •			0	4mg		·	•				4
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	IATION			
component parts						Dosage Form:	CAPSULE							
reverse numbered?		No				Dosage i oili.		U	Init of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 15			
latex-free?		Yes				Product Shape	Capsule, Size 3		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		No							Ampule					
correctional institution block?		Yes				Product Color	Light Blue		Glass		Minimum o	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	IN		Product Imprir	nt: C / 671	_	Vial Liquid Sgl					
If Unit Dose, is item bar coded to understand the hospital scanning?	unit dose for		la thia anadust assumed s					_	Vial Liquid Multi				ich package	type?
			Is this product covered u Trade Agreements Act (1	nder the	Na				Vial Powder Sql		48	Each	/Deels	
If Unit Dose, indicate NDC here:			1 rade rigicements riet (1	700.	No				Vial Power Multi			Inner/Cartor	/Pack	
									Other: Write In					
			FOR CENERIC DRIVE PRO	DDUCTS				<u> </u>	Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS				<u> </u>	Other: Write In					
			FOR GENERIC DRUG PRO	DDUCTS	Δ.	uthorized Conorio *	If Authorized Congric other			RMACY ORDER	/ BILL LINIT			
			FOR GENERIC DRUG PRO	DDUCTS	Au		If Authorized Generic, other		РНА	RMACY ORDER		Case		
I. Orange Book Rating:	AB	7	FOR GENERIC DRUG PRO	DDUCTS	Au		If Authorized Generic, other section fields are not applicable	Rec. sell unit to	PHA customer?	RMACY ORDER	Rx billing u	Case	асу:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Zanaflex	FOR GENERIC DRUG PRO	DDUCTS	Au			1 bottl	PHA customer? le of 150 tablets	RMACY ORDER		Case nit to pharm Each	acy:	
								_	PHA customer? le of 150 tablets	RMACY ORDER	Rx billing u	Case nit to pharm Each Gram	асу:	
			FOR GENERIC DRUG PRO					1 bottl	PHA customer? le of 150 tablets	RMACY ORDER	Rx billing u	Case nit to pharm Each	acy:	
	and?:	DRUG SUPPL'						1 bottl	PHA customer? e of 150 tablets Vial)	RMACY ORDER	Rx billing u	nit to pharm Each Gram Milliliter	acy:	
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?:	DRUG SUPPL'	Y CHAIN SECURITY ACT (I		RMATION GLN:	8902805000006		1 bottl	PHA customer? de of 150 tablets Vial)	AND PACKING IN	Rx billing u X	nit to pharm Each Gram Milliliter		Saleable #
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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



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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?					