

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

Version 2021							уре:	Post Launch Change		x Final Version			Date:	7/12/	/2021	
			PRODUCT INFORMAT	TION						SPECIAL HA	NDLING AND STO	RAGE REQUI	REMENTS*			
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA									a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN			ce):	20	2279	7495.104.1	· · · ·	7111271	u. remperatur	Temperature Range			between 20 and 25 C (68° – 77° F)			
Medical Device Class, if applica	, .,.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,-										(			
DUNS:	022490515									Other Temperature Range	Requirement					
Proprietary Name (If Applicable)	and Established N	ame: Zolmiti	riptan IR Tablets							(write in)	·					
Selling Unit NDC:	59746-432-16		Unit of Use NDC:			UPC:	3-59746	-432-16-4		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Zolmitriptan IR 2.	5mg 6ct Tablets								Is this product to be shipp	ed to customers on	ice?		No	1	
										Is this product to be shipp				No		
Active Ingredient(s):																
	b. Contact for temperature excursion questions:															
URL for Additional Product Inforr	prmation: www.cadista.com/products/full-product-list												Customer Service			
Address:	207 Kiley Drive					Address 2:			Number:			(800) 313-4623				
City:	Salisbury				State:	MD Zip: 21801			Group E-mail:				customer.service@cadista.com			
Key Contact:	Jackie Emershaw (410) 912-3722				Email: Fax:	Jackie.Emershaw@jubl.com (215) - 443 - 9646			c. Special regulations for product in any states?					Nie	1	
Phone Number:		Missaine Handockee			rax.	(215) - 443 - 9646			c. Special reg	No No						
Product Therapeutic Classification	on:	Migraine Headache	is .							Special returns requireme	nts for this product?			No		
	ADDITI	ONAL PRODUCT IN	FORMATION			PPODIICT D	ESCDID.	TION INFORMATION	d Store produ	int (unit of cale) unright?				No	1	
	— ADDIII	ONALT RODUCT IN		Discoul Obj.	2-1-	- PRODUCT D	LOCKIP	TION IN ORWATION	u. Store prodi	uct (unit of sale) upright?				No	]	
The product is?			Is the Product	Direct-Ship C	Jnly		0		. 01-1/11/-	Protect product (unit of	sale) from light?			No 04		
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit Dose		Size:	ь	count	e. Shelf life:	Initial shalf life at launah	(if different):			24	Months Months	
a product kit?		No	Orphan Drug Status				2	.5mg		Initial shelf life at launch	(ii dilierent).				Wionins	
if yes, list NDCs of		INU	FDA Approval Status			Strength:	-	Joney			ORDER INFORI	MATION				
component parts							Т	ABLET								
reverse numbered?		No				Dosage Form	1:			Unit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present				_	•		Bottle		1 carton of 6	6 tablets			
latex-free?		Yes				Product Shap	R. R	tound		X Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)		
preservative-free?		No				oaaot onap				Ampule						
correctional institution block?		Yes				Product Colo	r: L	ight Pink		Glass		Minimum o	rder quantity	?	Yes	
opioid?		No	Once to a Code to	IN				ND 7		Tube						
Cannabinoid?		No	Country of Origin	IIN		Product Impri	int:	CB7		Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	ah naakaga	tumo?	
If Unit Dose, is item bar coded to hospital scanning?	unit dose for	Yes	Is this product covered u	nder the						Vial Powder Sql		120	many of whi	cii package	typer	
If Unit Dose, indicate NDC here:					No					Vial Power Multi Inner/Carton/Pag			/Pack			
iii ciiii 2000, iiialoato 1120 iiolo.			_ ,							Other: Write In			Case	, aon		
			FOR GENERIC DRUG PRO	DDUCTS		<u> </u>			+							
									7							
					Au	uthorized Generic	*If Autho	orized Generic, other		Р	HARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating: AB					section fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:								
II. Generic Equivalent to What Brand?: Zomig							1 carton of 6 tablets			X Each						
·									(Write-in, e.g.	1 Vial)			Gram			
		DRUG SUPPL	Y CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION								Milliliter			
Does supplier meet DSCSA defin		rer?	Yes	_	GLN:	8902805000006				ITE	M AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:	0359746			1	Weight Lbs.		ions (US msr	-	Volume	Saleable #	
Other exemption - Write in:										110.g.n. 2.50.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?		10	No	_		riginal product			Item/Each:	0.03	3.07	1.96	0.98	5.90	1	
Is product sold by manufacturer's Has FDA granted waiver/exception			No No	-	-	irect from mfr? ce manufacturer for	r ron!	agad product	Box/Carton/B	undlo/						
If yes, attach documentation fro		roduct?	INO		Provide sour	ce manuracturer for	гераск	aged product	Inner Pack:	undie/				0.00		
ii yes, attaon accumentation no	mi i DA.								Case:							
		GTII	N AND HIBCC PRODUCT IN	IFORMATION					June 1	5.29	13.38	12.59	5.31	894.49	120	
									Pallet:					0.00		
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC			N-14		Unit of Use GTIN-14						0.00		
X Item/Each		1			003	59746432164										
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESALER USE ONLY:				
X Case		120			403	59746432162			1							
Pallet									Regular Cost			Vendor #:				
									Invoice Cost (	WAC) (\$)	\$50.00	Whsl. Code Fineline Co				
	-								As of date:			rineline Co	ue.			
									, is or uate.							
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSERT.	LABEL AND PHOTO OF P	PRODUCT PACKA	AGING and BARCODE.						



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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?						