

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

Version 2021						Introduction T	Гуре:	New Item		X Final	Version			Date:	11/08	/2022
			PRODUCT INFORMA	TION						SF	ECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name: Jubilant Cadista Pharmaceuticals Inc.					Applicat	tion:	ANDA	a. Temperatui	perature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA (drug): PMA/510(k)(med device): ANDA 216594								Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:																
DUNS:	022490515								1	Other Tempera	ture Range R	equirement				
Proprietary Name (If Applicable) a	and Established N	ame: Carba	mazepine ER Tablets							(write in)	-	·				
Selling Unit NDC:	59746-789-01		Unit of Use NDC:			UPC:	3-5974	46-789-01-5		Notes						
UDI			CVX Code:			MVX Code:										
Description: Carbamazepine ER 100mg 100ct Tablets								1	Is this product	to be shipped	to customers on ic	ce?		No		
												to customers on d			No	
Active Ingredient(s): Carbamazepine																
						b. Contact for	temperature e	xcursion que	stions:							
URL for Additional Product Information: <u>www.cadista.com/products/full-product-list</u>				Address 2:			Name: Customer Service									
Address:	207 Kiley Drive			State:				Number:				(800) 313-4623				
City:	Salisbury Katie Jones	,			Email:	MD Zip: 21801 Katie.Jones@jubl.com			Group E-mail:				customer.service@cadista.com			
Key Contact: Phone Number:	(215) 550-2824				Fax:	(215) 443-9646			c. Special regulations for product in any states?						No	
Product Therapeutic Classification		Anticonvulsant			-	(210) 440 3040			Special returns requirements for this product?				No			
Froduct Therapeutic Glassification		7 ti ti com v disam			1					Opecial returns	requirement	s for this product:			140	
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT	DESCRI	IPTION INFORMATION	d Store produ	uct (unit of sale	) unright?				No	
The product is?			Is the Product	Direct-Ship (	Only					•		a) from light?				
The product is? a legend device?		No	Is the Product	Neither	Jy			100 count	e. Shelf life:	Protect produ	or family of Sal	e, nom ilgnt?			No 24	Months
if yes, enter class #		INU	Orphan Drug Status	11010101		Size:		100 count	C. Onen me.	Initial shelf life	e at launch (it	different):			2-7	Months
a product kit?		No						100mg								
if yes, list NDCs of		1.14	FDA Approval Status			Strength:			ORDER INFORMATION							
component parts						Dosage Forn	m·	TABLET								
reverse numbered?		No				Dosage i on				Unit of Sale				NDC selling	unit?	
co-licensed?		No	Allergens Present							X Bottle			1 Case of 2			
latex-free?		Yes				Product Sha	ipe:	Round, Biconvex			Carton		(Write-in, e	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		No						Peach		Ampi			Minimum o	dor augntitu		Yes
opioid?		Yes				Product Cole	or:	Peach		Tube			winimum o	rder quantity	r	res
Cannabinoid?		No No	Country of Origin	US				CR 100'			iquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for	140	,g			Product Imp	rint:				iquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	inder the							Powder Sql		24	Each		***
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No	No			Vial Power Multi			Inner/Carton/Pack				
									] [	Othe	r: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS												
					Au	uthorized Generic		horized Generic, other			PH/	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:  II. Generic Equivalent to What Brand?:  Tegretol XR®				section fields are not applicable			Rec. sell unit to customer?  1 Bottle of 100 tablets				Rx billing unit to pharmacy:					
											X Each					
		DDUC CUDDI	Y CHAIN SECURITY ACT (	Dece A) INFO	MATION				(Write-in, e.g.	1 Vial)				Gram		
		DRUG SUFFL	T CHAIN SECURITT ACT (	D3C3A) INFOR	KWATION				<b>–</b>				Milliliter			
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes		GLN:	0359746000004					ITEM	AND PACKING IN	FORMATIO	١		
Is product exempt from DSCSA?			No		,	,1111										
If yes, select exemption:				_	GCP:	0359746			i			Dimensi	ons (US msn	nte )	Volume	Saleable #
Other exemption - Write in:					GOF.	0003140			1	W	eight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_	If ves. was o	riginal product			Item/Each:			· ·				
Is product sold by manufacturer's	exclusive distrib	utor?	No			irect from mfr?					0.06	1.50	1.50	2.34	5.27	1
Has FDA granted waiver/exception	n/exemption for p	roduct?	No		Provide sour	ce manufacturer fo	or repac	kaged product	Box/Carton/B	undle/					0.00	
If yes, attach documentation from	m FDA.								Inner Pack:						0.00	
									Case:		1.39	10.16	6.85	3.50	243.81	24
		GTI	N AND HIBCC PRODUCT I	NFORMATION												
Coloobia Hait of Manager	,	Salaabla Oosaaliis	LUDOO		0.71	N. 44		Helt of Helt OTINI 44	Pallet:						0.00	
Saleable Unit of Measure		Saleable Quantity	HIBCC			N-14		Unit of Use GTIN-14								
Item/Each Box/Carton/Bundle/Inner Pack					59746789015			COST INFORMATION				WHOLESALER USE ONLY:				
X Case	24 4035			59746789013	746789013			COST INFORMATION				WHOLESALER USE ONET:				
Pallet		2.7			100				Regular Cost				Vendor #:			
											Whsl. Code	#:				
	1												Fineline Co			
									As of date:							
1									Ш							
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.  *Please provide any additional information on page 2  See new p. 3 for Designated Drop Ship Only Signature:																



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## Version 2021 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 REMS: Is this a reportable quantity? 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 #:	Fax Number: Fax Number: Phone No.: Site Address:  Name: Phone: Phone: rges or Other Designated Drop Ship Fees:	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:  Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each orde		Overnight receipt available:						
Drop Ship service fee billed with each order Drop Ship miscellaneous fees billed: Comments:	T	PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday  Priority Overnight receipt available:						
Cla	ss of Trade Restriction:	PO Receipt Cut off time:						
No restriction: Select YES if sold to retail ph Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician Restricted from US territories? (explain in c Comments:	narmacy, hospitals, clinics and physician offices a offices only: comments)	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply:  Other fees apply:						
Other Data Inf	ormation 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?						