

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

Version 2021						Introduction Ty	pe: Post	Launch Change	]	X Final Version			Date:	6/17	/2024
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN				AN	DA 216594					Temperature Range	Controlled Room		and 25 C (68	8° – 77° F)	
Medical Device Class, if applica	able:														
DUNS:	022490515									Other Temperature Range	Requirement				
Proprietary Name (If Applicable)		me: Carba	amazepine ER Tablets							(write in)					
Selling Unit NDC: UDI	59746-791-01		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-59746-791-01	-8	-	Notes					
						WVX Code.			1					_	
Description:	Carbamazepine E	R 400mg 100ct Tab	olets							Is this product to be shippe				No No	-
Active Ingredient(s):		Carbamazepine							+	Is this product to be shippe	ed to customers on	dry ice?		INO	_
Active ingredient(s).		Carbamazepine							b. Contact fo	r temperature excursion q	uestions:				
URL for Additional Product Inforr	mation:	www.cadista.co	om/products/full-product	t-list					Name: Customer Service						
Address:	790 Township Line	e Road					Suite 325			Number:		(800) 313-4			
City:	Yardley				State:		<b>Zip</b> : 19067			Group E-mail:		<u>customer</u>	.service@ca	adista.com	
Key Contact: Phone Number:	Customer Service (800) 313-4623	!			Email: Fax:	customer.service@cadista.com N/A		a Cuasial sa					No		
Product Therapeutic Classification		Anticonvulsant			rax:	IN/A			c. Special reg	gulations for product in an Special returns requirement	-	,		No	-
Product Therapeutic Classification	on:	Anticonvulsant								Special returns requiremen	nts for this product			INO	
	ADDITIO	ONAL PRODUCT I	NFORMATION			PRODUCT D	ESCRIPTION IN	FORMATION	d Store prod	uct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	inly				ar otoro prod	Protect product (unit of s	ala) from light?			No	1
a legend device?		No	Is the Product	Neither	THY		100 coun	t	e. Shelf life:	Protect product (unit or s	sale) from light?			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:	100 0001	ı	C. Onen me.	Initial shelf life at launch	(if different):				Months
a product kit?		No				Ctuan ath.	400mg				(				
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFOR	MATION			
component parts						Dosage Form:	TABLET								
reverse numbered?		No	All B							Unit of Sale			NDC selling	unit?	
co-licensed?		No Yes	Allergens Present				Round, E	ticonyey		X Bottle Box/Carton		1 Bottle of 1	g. 1 Box of 1	In Miale)	
preservative-free?		No				Product Shap	e:	JICOTIVEX		Ampule		(vviite-iii, e	.g. 1 D0x 01 1	o viais)	
correctional institution block?	•	Yes				Description Color	Peach			Glass		Minimum o	rder quantity	v?	Yes
opioid?		No				Product Color	•			Tube				•	
Cannabinoid?		No	Country of Origin	US		Product Impri	'CR 400'			Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					. roudot impir				Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered u		NI.					Vial Powder Sql		24	Each	. /D I	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	IAA)?	No					Vial Power Multi Other: Write In			Inner/Cartor Case	n/Pack	
			FOR GENERIC DRUG PR	ODUCTS					1	Other. Write III			Case		
			TOR GENERIC DROG FR	000013											
					Au	uthorized Generic	*If Authorized G	eneric, other		Р	HARMACY ORDE	R / BILL UNIT			
I. Orange Book Rating:	and in fields are not and inchin					Rec. sell unit to customer? Rx billing unit to pharmacy:									
II. Generic Equivalent to What Bra		Tegretol XR®								ottle of 100 tablets		X	Each	iuoy.	
									(Write-in, e.g				Gram		
		DRUG SUPP	PLY CHAIN SECURITY ACT (	DSCSA) INFOR	MATION								Milliliter		
				_											
Does supplier meet DSCSA defin		er?	Yes No	_	GLN:	0359746000004				ITE	M AND PACKING	INFORMATIO	N		
Is product exempt from DSCSA?			INU												
If yes, select exemption:					GCP:	0359746				Weight Lbs.		sions (US msı	•	Volume	Saleable #
Other exemption - Write in: Is product repackaged?			No		If you was a	riginal product purch	anned .		Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product sold by manufacturer's	's exclusive distribu	itor?	No		direct from n		laseu		item/Lacii.	0.20	1.87	1.87	3.77	13.18	1
Has FDA granted waiver/exception			No	1		ce manufacturer for	repackaged pr	oduct	Box/Carton/E	Bundle/				0.00	
If yes, attach documentation fro	om FDA.								Inner Pack:					0.00	
									Case:	1.81	12.28	8.27	4.92	499.78	24
		GT	TIN AND HIBCC PRODUCT II	NFORMATION							72.20	J.L.			
Saleable Unit of Measure	_	alaahla O	LUBCC			INI 4.4	11-0-4	Usa CTINI 44	Pallet:					0.00	
X Item/Each	S	aleable Quantity	HIBCC			IN-14 859746791018	Unit of	Use GTIN-14							
	X Item/Each 1 U0359746791018 U0359746791018							COST INFORMATION WHOLESALER USE ONLY:							
X Case		24			403	59746791016									
Pallet									Regular Cost			Vendor #:			
									Invoice Cost	(WAC) (\$)	\$160.00	Whsl. Code			
												Fineline Co	de:		
									As of date:			Fineline Co	ode:		
									As of date:			Fineline Co	ode:		
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza	ard letter PACKAGE I	NSERT I AREI	AND PHOTO OF		AGING and BARCODE		Fineline Co	ode:		



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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?	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
Is the product a CA Prop 65 carcinogen?  No	Organic Corrosive Inorganic Oxidizer							
Is the product a CA Prop 65 reproductive toxicant?  Does the product label bear a CA Prop 65 warning?  No	Inorganic Oxidizer Steroid/Androgen Contact Hazard							
boes the product label bear a OATTOP to warning:	Ornaci Tazard							
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No							
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:							
(If yes, attach SDS with special instructions.)	NFPA Storage Level:							
e. Does the product contain DEHP?								
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?							
(if yes, answer a-e below and provide SDS)	If yes, indicate which:							
a. UN/Identification Number b. Proper Shipping Name								
c. DOT Hazard Class	Hazardous Waste Identification							
d. Packing Group								
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics							
Is this product regulated for shipment by IATA?								
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS							
a. UN/Identification Number								
b. Proper Shipping Name	Is there a REMS on this product?							
c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry?  Website URL:							
e. Inhalation Hazard?	Website ORL.							
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? No	REMS:							
RQ Threshold:	REMS Program Manager Name: Phone:							
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:							
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:							
No (if yes, identify method below)  Limited Quantity	Provider Name: DEA #: Site Enrollment Number assigned NCPDP#:							
Consumer Commodity, ORM-D	by Supplier: NPI #:							
Small Quantity (49 CFR 173.4)								
Special Permit; DOT-SP	Comments							
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#	Registry:							
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:							
	Comments							
Is the Product Controlled Substance 2	RETURN INSTRUCTIONS							
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	KETORI NOTIONS							
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:	Consider outletions or returns continued for this							
Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states?							
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?							
Comments:								
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:							
- INIGCLELAT								



## **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 S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:		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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?