

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

Version 2024						Introduction Type	:		Final Version			Date:	12/19/	2024
			PRODUCT INFORMAT	TION					SPECIAL HAN	NDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Jubilant Cadista F	harmaceuticals Inc.				Application	ANDA	a. Temperature – Indica	te the USP temp	erature range for th	is product			
Application Number for NDA/ANI				NDA 505(b) Type: NOT APPLICABLE				ture Range	Controlled Room -		and 25 C (68	° – 77° F)		
Medical Device Class, if applicab		(,				(., ),		1	aro rango	-				
DUNS:	118694141							Other To	mperature Range	Descrisement				
Proprietary Name (If Applicable) a		ma: Carba	mazepine ER Tablets						te in)	Requirement				
Selling Unit NDC:	59746-791-01	ille. Calba	Unit of Use NDC:			UPC: 3-5	9746-791-01-8		ie iii)					
	39740-791-01					MVX Code:	19740-791-01-0	Notes						
ODI	UDI CVX Code: MVX Co													
Description:	Is this pro	oduct to be shippe	d to customers on ic	e?		No								
								Is this pro	duct to be shippe	d to customers on d	y ice?		No	
Active Ingredient(s):		Carbamazepine												
								b. Contact for temperat	ure excursion qu	estions:				
URL for Additional Product Inform			m/products/full-product	-list				Name:			Customer Se			
Address:		90 Township Line Road			Address 2:         Suite 325           State:         PA         Zip: 19067			Number:			(800) 313-46			
City:	Yardley				State:		Group E	mail:		customer.	ervice@ca	<u>dista.com</u>		
Key Contact:	Customer Service	•			Email:	customer.service(	<u>Dcadista.com</u>	<u> </u>						
Phone Number:	(800) 313-4623				Fax:	N/A		c. Special regulations for product in any states?						
Product Therapeutic Classification	n:	Anticonvulsant						Special re	eturns requiremen	its for this product?			No	
								_						
	ADDITI	ONAL PRODUCT IN	IFORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product (unit o	f sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly			Protect r	roduct (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither			100 count	e. Shelf life:		,			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:			elf life at launch (	(if different):				Months
a product kit?		No					400mg			(				
if yes, list NDCs of		110	FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts							TABLET							
reverse numbered?		No				Dosage Form:		Unit of S	ale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Bottle of 10			
latex-free?		Yes					Round, Biconvex		Box/Carton			g. 1 Box of 10	) Vials)	
preservative-free?		No				Product Shape:			Ampule		, , , , ,		,	
correctional institution block?		Yes					Peach		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube				I.	
Cannabinoid?		No	Country of Origin	India			'CR 400'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for	110	,g			Product Imprint:			Vial Liquid Multi		If Yes. how	many of whi	ch package t	/pe?
hospital scanning?	4000 101		Is this product covered up	nder the					Vial Powder Sql			Each	<b> </b> g	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No				Vial Power Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS				4						
			TON OZNZKIO DROG TRO	3300.0										
					Δut	horized Generic *If	Authorized Generic, other	PHARMACY ORDER / BILL UNIT						
			_	Authorized Generic in Authorized Generic, other section fields are not applicable										
I. Orange Book Rating: AB			LVDO				Rec. sell unit to custon			Rx billing u		acy:		
II. Generic Equivalent to What Brand?:  Tegretol XR®							1 Bottle of 100	tablets		Х	Each			
		DRUG GURRI	LY CHAIN SECURITY ACT (	DECEAL INFOR	MATION			(Write-in, e.g. 1 Vial)				Gram		
		DRUG SUPPI	LT CHAIN SECURITT ACT (	JSCSA) INFOR	WATION			HCPCS J-Code:				Milliliter		
Dana assembliar mant DCCCA definite			Yes	7	CL N.	0359746000004			ITEN	M AND PACKING IN	FORMATION	i		
Does supplier meet DSCSA definit	tion of manufactur	err	No	-	GLN:	0359746000004			IIEN	W AND FACKING IN	FURMATION			
Is product exempt from DSCSA?			INU											
If yes, select exemption:					GCP:	0359746			Weight Lbs.	Dimensio	ons (US msm	ts.)		Saleable #
Other exemption - Write in:									Weight Ebs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			ginal product purchas	sed	Item/Each:	0.20	1.87	1.87	3.77	13.183313	1
Is product sold by manufacturer's	exclusive distribu	itor?	No	_	direct from mf					1.4.				
Has FDA granted waiver/exception	n/exemption for pr	oduct?	No		Provide sourc	e manufacturer for re	packaged product	Box/Carton/Bundle/					0	
								Inner Pack:						
If yes, attach documentation from	n FDA.							Case:				5.91	648.97001	24
If yes, attach documentation from	n FDA.							Case:	3.03	12.68	8.66			
if yes, attach documentation from	n FDA.	GT	IN AND HIBCC PRODUCT IN	IFORMATION					3.03	12.68	8.66		0	
				IFORMATION				Pallet:	3.03	12.68	8.66			
saleable Unit of Measure	RFID tag(Y/N)	Saleable	IN AND HIBCC PRODUCT IN	IFORMATION	GTIN	J-14	Unit of Use GTIN-14		3.03	12.68	8.66		U	
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity		IFORMATION			Unit of Use GTIN-14		3.03	12.68	8.66		0	
Saleable Unit of Measure		Saleable		IFORMATION		J-14 9746791018	Unit of Use GTIN-14	Pallet:		12.68				
Saleable Unit of Measure  X	RFID tag(Y/N)	Saleable Quantity		IFORMATION	0035	9746791018	Unit of Use GTIN-14	Pallet:	3.03	12.68			ER USE ONL	<b>′</b> :
Saleable Unit of Measure  X Item/Each Box/Cartor/Bundle/Inner Pack X Case	RFID tag(Y/N)	Saleable Quantity		IFORMATION	0035		Unit of Use GTIN-14	Pallet:		12.68				<b>'</b> :
Saleable Unit of Measure  X	RFID tag(Y/N)	Saleable Quantity		IFORMATION	0035	9746791018	Unit of Use GTIN-14	Pallet:  COS' Regular Cost			Vendor #:	WHOLESALE		<b>'</b> :
Saleable Unit of Measure  X Item/Each Box/Cartor/Bundle/Inner Pack X Case	RFID tag(Y/N)	Saleable Quantity		IFORMATION	0035	9746791018	Unit of Use GTIN-14	Pallet:			Vendor #: Whsl. Code	WHOLESALE		<b>'</b> :
Saleable Unit of Measure  X Item/Each Box/Cartor/Bundle/Inner Pack X Case	RFID tag(Y/N)	Saleable Quantity		IFORMATION	0035	9746791018	Unit of Use GTIN-14	Pallet:  COST  Regular Cost Invoice Cost (WAC) (\$)			Vendor #:	WHOLESALE		í:
Saleable Unit of Measure  X Item/Each Box/Cartor/Bundle/Inner Pack X Case	RFID tag(Y/N)	Saleable Quantity		IFORMATION	0035	9746791018	Unit of Use GTIN-14	Pallet:  COS' Regular Cost			Vendor #: Whsl. Code	WHOLESALE		<i>r</i> :
Saleable Unit of Measure  X Item/Each Box/Cartor/Bundle/Inner Pack X Case	RFID tag(Y/N)	Saleable Quantity 1 24		IFORMATION	0035	9746791018	Unit of Use GTIN-14	Pallet:  COST  Regular Cost Invoice Cost (WAC) (\$)			Vendor #: Whsl. Code	WHOLESALE		f:
Saleable Unit of Measure  X Item/Each Box/Cartor/Bundle/Inner Pack X Case	RFID tag(Y/N)	Saleable Quantity	HIBCC		0035 4035	59746791018 59746791016		Pallet:  COS'  Regular Cost Invoice Cost (WAC) (\$)  As of date:	INFORMATION		Vendor #: Whsl. Code	WHOLESALE		<b>:</b>
Saleable Unit of Measure  X Item/Each Box/Cartor/Bundle/Inner Pack X Case	RFID tag(Y/N) N	Saleable Quantity  1  24	HIBCC		0035 4035	9746791018 9746791016 d letter, PACKAGE INS	Unit of Use GTIN-14  ERT, LABEL AND PHOTO OF I	Pallet:  COS'  Regular Cost Invoice Cost (WAC) (\$)  As of date:	INFORMATION  BARCODE.		Vendor #: Whsl. Code	WHOLESALE		·



Version 2024

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

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?					