

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

Version 2024						Introduction Type:			Final Version			Date:	12/19/	2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Jubilant Cadista F	harmaceuticals Inc.				Application:	ANDA	a. Temperature – Indica	ate the USP tempe	erature range for th	is product.			
Application Number for NDA/ANDA/BLA; PMA/510(k): 216594 NDA 505(b) Type: NOT APPLICABLE							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:														
DUNS:	118694141							Other Te	mperature Range F	Requirement				
Proprietary Name (If Applicable) a		ime:							ite in)	4				
Selling Unit NDC:	59746-789-01		Unit of Use NDC:	I		UPC: 3-59	9746-789-01-5	Notes	•					
UDI			CVX Code:			MVX Code:		11						
								le this pro	nduct to be ebipped	d to customers on ic			No	
Description: Carbamazepine ER 100mg 100ct Tablets										to customers on d			No	
Active Ingredient(s): Carbamazepine						is this pix	to 20 0ppct	Juotoo.o 011 u	., .50.					
Saladinacopino									ure excursion que	estions:				
URL for Additional Product Information: www.cadista.com/products/full-product-list			:-list				Name:			Customer Se	rvice			
Address: 790 Township Line Road				Address 2: Suite 325			Number			(800) 313-46	23			
City:	Yardley				State:		p: 19067	Group E-mail: customer.service@cadista.com						
Key Contact:	Customer Service Email: customer.service@cadista.com													
Phone Number:	(800) 313-4623				Fax:	N/A		c. Special regulations f					No	
Product Therapeutic Classification	n:	Anticonvulsant						Special r	eturns requirement	s for this product?			No	
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product (unit of	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly	ĺ		Protect	product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			1 5.25.		Initial sh	elf life at launch (i	if different):				Months
a product kit?		No				Strength:	100mg				ATION			
if yes, list NDCs of			FDA Approval Status			1	TADLET			ORDER INFORM	ATION			
component parts reverse numbered?		No				Dosage Form:	TABLET	Unit of S	alo		What is the	NDC sallina	unit?	
co-licensed?			Allergene Brecent						Bottle		1 Bottle of 10		unitr	
latex-free?		No Yes	Allergens Present				Round, Biconvex	_ ^_	Box/Carton			g. 1 Box of 10) \/iale\	
preservative-free?		No				Product Shape:	Round, Biconvex		Ampule		(vviite-iii, e.	g. 1 DOX 01 10	, viais)	
correctional institution block?		Yes					Peach		Glass		Minimum or	der quantity	?	
opioid?		No				Product Color:	. 64611		Tube			aor quarrity		
Cannabinoid?		No	Country of Origin	India		Book door to be constant.	CR 100'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		· -			Product Imprint:			Vial Liquid Multi		If Yes, how	many of which	ch package ty	/pe?
hospital scanning?			Is this product covered u						Vial Powder Sql		24	Each	-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	ΓAA)?	No				Vial Power Multi			Inner/Carton	/Pack	
						<u> </u>			Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
Authorized Generic *If Authorized Generic, other						PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating: AB				section fields are not applicable			Rec. sell unit to custon		-	Rx billing ur		ıcy:		
II. Generic Equivalent to What Brand?: Tegretol XR®							1 Bottle of 10 (Write-in, e.g. 1 Vial)	0 tablets		Х	Each			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION												Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFORI	MATION			HCPCS J-Code:		1		Milliliter		
Dogs supplier most DSCSA definiti	ition of manufact	or?	Yes		GLN:	0359746000004			ITEM	I AND PACKING IN	IEORMATION	ı		
Does supplier meet DSCSA definit Is product exempt from DSCSA?	nion or manuractur	eit	No	_	GLN:	0359740000004			TIEN	HAND PACKING IN	I-OKWATION			
· ·			140					-						
If yes, select exemption:					GCP:	0359746			Weight Lbs.		ons (US msm	-		Saleable #
Other exemption - Write in:			No		w	taland and door and				Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	e exclusive dietrit.	itor?	No		If yes, was ori direct from mi	iginal product purchas	ea	Item/Each:	0.06	1.50	1.50	2.34	5.274	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	_		rr ? se manufacturer for rep	ackaged product	Box/Carton/Bundle/						
If yes, attach documentation from		oudet :	140		r roviue sourc	e manuracturer for rep	vackayeu product	Inner Pack:					0	
you, attach accumentation not	27.			l.				Case:				1.50		
		_GTIN	I AND HIBCC PRODUCT II	NFORMATION				1	1.39	10.55	7.24	4.53	346.01046	24
								Pallet:					0	
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTIN	N-14	Unit of Use GTIN-14						0	
1.1	,	Quantity												
					0035	59746789015								
X Item/Each	N	1						cos	TINFORMATION		, T	WHOLESALE	ER USE ONLY	' :
Box/Carton/Bundle/Inner Pack														
Box/Carton/Bundle/Inner Pack X Case	N	24			4035	59746789013								
Box/Carton/Bundle/Inner Pack					4035	59746789013		Regular Cost			Vendor #:	,,		
Box/Carton/Bundle/Inner Pack X Case					4035	59746789013		Regular Cost Invoice Cost (WAC) (\$)		\$45.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case					4035	59746789013		Invoice Cost (WAC) (\$)		\$45.00				
Box/Carton/Bundle/Inner Pack X Case					4035	59746789013				\$45.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case					4035	59746789013		Invoice Cost (WAC) (\$)		\$45.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		24	Attach conv of SAFETY DA	ATA SHEET (SO			ERT, LABEL AND PHOTO OF F	Invoice Cost (WAC) (\$) As of date:	BARCODE	\$45.00	Whsl. Code			



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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): 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



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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?					