

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

	2021 Introduction Type: Post Launch Change							nange		x Final Version			Date:	7/12/	/2021	
			PRODUCT INFORMAT	ΓΙΟΝ						SPECIAL HAND	LING AND STOR	AGE 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			·o)·	21	2218	7.000.00	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				Controlled Room -		and 25 C (68	3° – 77° F)		
Medical Device Class, if applical		ruo ro(n)(moa ao rio	Ψ,							inportation realigo						
DUNS:	022490515				1				Oth	ner Temperature Range R	equirement					
Proprietary Name (If Applicable) a		me: Clomin	oramine HCI Capsules		1				Out	(write in)	equirement					
Selling Unit NDC:	59746-711-90	iic.	Unit of Use NDC:			UPC: 3	3-59746-711-90-0		Not							
UDI	007 10 7 1 1 00		CVX Code:			MVX Code:	, , , , , , , , , , , , , , , , , , , ,									
-												_				
Description:	Clomipramine Hydr	rochloride 50mg 90ct	Capsules							his product to be shipped				No		
A ative Improvedient(a)		Clomipramine Hydro	ochlorido						is tr	his product to be shipped	to customers on a	iry ice?		No		
Active Ingredient(s):		Cionipianine Hydro	Jonionae						h Contact for tom	perature excursion que	etione:					
URL for Additional Product Inforn	mation:	www.cadista.cor	m/products/full-product	+ liet					Nar		stions.	Customer Se	arvice			
Address:	207 Kiley Drive	www.cauista.com	ii/products/ruii-product	<u>t-list</u>	1	Address 2:				mber:		(800) 313-46				
City:	Salisbury					MD Zip : 21801			Group E-mail:				customer.service@cadista.com			
Key Contact:	Jackie Emershaw	pershaw			State: Email:	Jackie.Emershaw@jubl.com			O.C	oup E man.		customer.	3CT VICE (WCC	dista.com		
Phone Number:	(410) 912-3722					Fax: (215) - 443 - 9646			c. Special regulati	ions for product in any s	states?			No	1	
Product Therapeutic Classification		Antidepressant				()				ecial returns requirements				No	1	
Troduct Therapeatic Glassificatio	····	7 initiaoprocedin							Орс	colai retarrio reguiremente	nor tino product:			110		
	ADDITIO	NAL PRODUCT INF	FORMATION			PRODUCT DE	SCRIPTION INFORMATION	ION	d. Store product (unit of sale) upright?				No	1	
The mandatation				Direct-Ship (Only						a) fram Part o				1	
The product is? a legend device?			Is the Product	Neither	Only		90 count bottles		e. Shelf life:	otect product (unit of sal	e) from light?			No		
-		No	Is the Product	Neither		Size:	90 count bottles			del elegioni de la comete de				24	Months	
if yes, enter class #			Orphan Drug Status				50mg		init	ial shelf life at launch (if	airrerent):				Months	
a product kit? if yes, list NDCs of		No	EDA Approval Status			Strength:	burng				ORDER INFORM	ATION				
component parts			FDA Approval Status				CAPSULES				ORDER IN ORM	ATION				
reverse numbered?		No				Dosage Form:	CAI SOLLS		Hni	it of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							X Bottle		1 bottle of 90		unit.		
latex-free?		Yes	Allergens Fresent				Capsule, Size 1			Box/Carton			g. 1 Box of 1	0 Vials)		
preservative-free?		No				Product Shape	e: Oupsuic, Oize 1			Ampule		(vviite iii, e.	g. 1 Dox 01 1	, viais)		
correctional institution block?		Yes					White			Glass		Minimum o	der quantity	12	Yes	
opioid?		No				Product Color:	: ***********************************			Tube		Million Ci	uci quantity		103	
Cannabinoid?		No	Country of Origin	US			C / 711			Vial Liquid Sql						
If Unit Dose, is item bar coded to u		IVO	,g			Product Imprir	nt:			Vial Liquid Multi		If Yes, how	many of wh	ich package i	type?	
hospital scanning?	u doco .c.		Is this product covered up	nder the						Vial Powder Sql			Each		.,,,,,	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	ΓAA)?	Yes					Vial Power Multi			Inner/Cartor	/Pack		
	'		_							Other: Write In			Case			
			FOR GENERIC DRUG PRO	ODUCTS												
					Au	uthorized Generic *	If Authorized Generic, other	ner		PHA	ARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB		section fields are not applicable						Rec. sell unit to cu	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Bra									1 bottle of 90 capsules				X Each			
		Anafranil							1 bottle o				Each			
		Anafranil								of 90 capsules			Each Gram			
			Y CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION				1 bottle o (Write-in, e.g. 1 Via	of 90 capsules						
		DRUG SUPPLY	·	DSCSA) INFOR						of 90 capsules (al)		X	Gram Milliliter			
Does supplier meet DSCSA defini		DRUG SUPPLY	Yes	DSCSA) INFOR	RMATION GLN:	0359746000004				of 90 capsules (al)	AND PACKING IN	X	Gram Milliliter			
Does supplier meet DSCSA defini		DRUG SUPPLY	·	DSCSA) INFOR		0359746000004				of 90 capsules (al)	AND PACKING IN	X	Gram Milliliter			
Is product exempt from DSCSA? If yes, select exemption:		DRUG SUPPLY	Yes	DSCSA) INFOR		0359746000004				of 90 capsules al)	Dimensi	X NFORMATION ons (US msn	Gram Milliliter	Volume	Saleable #	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:		DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP:	0359746			(Write-in, e.g. 1 Vi	of 90 capsules (al)		X	Gram Milliliter	Volume (Cube)	Saleable # Pieces	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was o	0359746				of 90 capsules al)	Dimensi	X NFORMATION ons (US msn	Gram Milliliter			
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distribut	DRUG SUPPLY	Yes No No	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	0359746 riginal product			(Write-in, e.g. 1 Via	of 90 capsules al) ITEM Weight Lbs. 0.14	Dimensi Depth	X IFORMATION ons (US msn Width	Gram Milliliter	(Cube)	Pieces	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distribut on/exemption for pro	DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	0359746	repackaged product		(Write-in, e.g. 1 Vi	of 90 capsules al) ITEM Weight Lbs. 0.14	Dimensi Depth	X IFORMATION ons (US msn Width	Gram Milliliter	(Cube)	Pieces	
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each BoxCarton/Bundle/Inner Pack X case	s exclusive distribut on/exemption for pro m FDA.	DRUG SUPPLY er? tor? oduct? GTIN aleable Quantity	Yes No No No No No No		GLN: GCP: If yes, was oi purchased di Provide sour	0359746 riginal product irect from mfr? rce manufacturer for IN-14		-14	(Write-in, e.g. 1 Via	of 90 capsules al) ITEM Weight Lbs. 0.14 4.33 COST INFORMATION	Dimension Depth 1.9	X IFORMATION Ons (US msm Width 1.9	Gram Milliliter N Ints.) Height 4 5	(Cube) 14.44 0.00 445.63 0.00	Pieces 1 24	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X tem/Each BoxCarton/Bundle/Inner Pack X case	s exclusive distribut on/exemption for pro m FDA.	DRUG SUPPLY er? tor? oduct? GTIN aleable Quantity	Yes No No No No No No		GLN: GCP: If yes, was oi purchased di Provide sour	0359746 riginal product irect from mfr? rce manufacturer for IN-14		-14	(Write-in, e.g. 1 Via	of 90 capsules al) ITEM Weight Lbs. 0.14 4.33 COST INFORMATION	Dimension Depth 1.9 11.5	X JEORMATION Ons (US msn Width 1.9 7.75	Gram Milliliter N Ints.) Height 4 5 WHOLESAL #:	(Cube) 14.44 0.00 445.63 0.00	Pieces 1 24	
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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



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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					
Class of Trade Restriction: 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: Other Data Information Required to Process PO:	Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply: 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?					