

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

Version 2021						Introduction Typ	Post Launch Change		X	Final Version			Date:	6/9/2	2023
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*	*	
Company Name: Jubilant Cadista Pharmaceuticals Inc. Applica				Applicatio	n: ANDA	a. Temperatu	re – Indica	ate the USP tempe	erature range for t	his product.					
Application Number for NDA/AN			ce):	212	2218		1	u. romporata		ture Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat			,						•	0					
DUNS:	022490515							-	Other Te	mperature Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established N	ame: Clomi	ipramine HCI Capsules						(wri	te in)					
Selling Unit NDC:	59746-712-90		Unit of Use NDC:				-59746-712-90-7		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Clomipramine HC	CI 75mg 90ct Capsule	es						Is this pro	oduct to be shipped	d to customers on i	ce?		No	1
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Clomipramine Hydrochloride															
URL for Additional Product Information: www.cadista.com/products/full-product-list								b. Contact for temperature excursion questions: Name: Customer Service							
URL for Additional Product Inform Address:	207 Kiley Drive	www.cadista.co	m/products/full-produc	<u>t-list</u>	1	Address 2:			Name: Number:			(800) 313-46			
City:	Salisbury				MD	Group E-mail:				customer.service@cadista.com					
Key Contact:	Customer Service				Email:	customer.service	-	0.049 -			<u>customer</u> .	<u>service e</u> co	uista.com		
Phone Number:	(800) 313-4623				Fax:	N/A	c. Special reg	gulations f	or product in any	states?			No	1	
Product Therapeutic Classification	n:	Antidepressant			1				Special r	eturns requirement	ts for this product?			No	-
-					1										1
	ADDIT	IONAL PRODUCT IN	FORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store prod	uct (unit c	of sale) upright?				No]
The product is?			Is the Product	Direct-Ship C	Inly			11	Protect p	product (unit of sa	ale) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	90 count	e. Shelf life:		-	-			24	Months
if yes, enter class #			Orphan Drug Status			5126.			Initial sh	elf life at launch (if different):				Months
a product kit?		No				Strength:	75mg								
if yes, list NDCs of			FDA Approval Status			J. J. J.	0				ORDER INFORM	NATION			
component parts reverse numbered?		No				Dosage Form:	Capsule		Unit of S	ala		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 Bottle of 9		unit:	
latex-free?		Yes	Allergens Tresent				Capsule, Size 1			Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Shape				Ampule		(J		
correctional institution block?		Yes				Product Color:	Light Yellow			Glass		Minimum o	rder quantity	?	Yes
opioid?		No		-		Froduct Color.				Tube					
Cannabinoid?		No	Country of Origin	US		Product Imprin	C 712'			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for					•				Vial Liquid Multi			many of whi	ch package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (Vaa					Vial Powder Sql Vial Power Multi		24	Each Inner/Carton	/De els	
Il Unit Dose, Indicate NDC here.			Trade Agreements Act (TAA)?	Yes					Other: Write In			Case	Pack	
			FOR GENERIC DRUG PR	ODUCTS		1				Outer: Write III			Ouse		
			TOR CENERIO DROGTR	000010											
					Au	uthorized Generic *	If Authorized Generic, other			PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					s	ection fields are not applicable	Rec. sell unit	to custon	ner?		Rx billing u	nit to pharma	acv:	
II. Generic Equivalent to What Brand?: Anafranil®				1 Bottle of 90 Capsules				x Each							
						(Write-in, e.g. 1 Vial)			-	Gram					
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION								Milliliter		
	4		Voc	_		025074000004			_	177-1			M		
Does supplier meet DSCSA definit Is product exempt from DSCSA?	uon or manufactu	irer?	Yes	-	GLN:	0359746000004					I AND PACKING I	NFORMATIO	IN		
		L	110								D 1	ana (110			
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ions (US msn		Volume (Cubo)	Saleable #
Other exemption - Write in: Is product repackaged?			No		If yoe was a	riginal product purch	bose	Item/Each:			Depth	Width	Height	(Cube)	Pieces
Is product sold by manufacturer's	exclusive distrib	utor?	No	-	direct from n		aseu	nem/Each.		0.14	2	2	4	16.00	1
Has FDA granted waiver/exception			No	-		ce manufacturer for r	epackaged product	Box/Carton/B	Bundle/					0.00	
If yes, attach documentation from		L						Inner Pack:						0.00	
								Case:		4.41	12.5	8.5	5.25	557.81	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION											
Saleable Unit of Measure								Pallet:						0.00	
X Item/Each	:	Saleable Quantity	HIBCC			IN-14	Unit of Use GTIN-14								
Box/Carton/Bundle/Inner Pack								COST INFORMATION				WHOLESALER USE ONLY:			
X Case	24 40359746712905										WHOLESALER USE ONET.				
Pallet								Regular Cost				Vendor #:			
								Invoice Cost			\$437.40	Whsl. Code			
								11				Fineline Co	de:		
	-							As of date:							
								11				1			
μ					(C) os non k	A Latter DACKAGE				PARCORE		ļ			
*Please provide any additional infe	ormation on no	. 2	Autach copy of SAFE (Y D)	ATA SHEET (SD	or non haza (د		SERT, LABEL AND PHOTO OF	PRODUCT PACKA							
Flease provide any additional into	ormation on page	· 2 .				See new p. 5 for De	esignated Drop Ship Only.		Signatur	е.					

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

Version 2021 Fo	or Designated Drop Ship Only Products, Please Use Page 3
MAT	FERIAL HAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	No SDS Hazard Classification No Organic Corrosive No Inorganic Oxidizer No Steroid/Androgen Contact Hazard No Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No No NFPA Storage Level: Image: Contact Hazard
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which: Hazardous Waste Identification Image: No EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity	No REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? No Website URL: No No Med Guide Required Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) No REMS: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned DEA #:
Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP# ADD'L STORAGE INFORMATION	by Supplier: NPI #: Comments
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION: No CLASS OF TRADE RESTRICTION:	No RETURN INSTRUCTIONS No Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:
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:	Yes Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? SCELLANEOUS NOTES and/or Image of Product Barcode:



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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 #: 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: Image: Comparison of the co
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: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?