

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

						Introduction Type:	Post Launch Change		x Final Version			Date:		2021
			PRODUCT INFORMA	TION					SPECIAL HAND	LING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	Jubilant Cadista F	Pharmaceuticals Inc.				Application:	ANDA	a. Temperature	e - Indicate the USP temper	ature range for t	his product.			
Application Number for NDA/AN			ce):	212218						Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applica		,								-		(
DUNS:	022490515							"	Other Temperature Range R	equirement				
Proprietary Name (If Applicable) a		ame: Clomir	pramine HCl Capsules					1	(write in)					
Selling Unit NDC:	59746-710-90		Unit of Use NDC:			UPC: 3-597	46-710-90-3		Notes					
UDI			CVX Code:			MVX Code:								
	01							1			_			
Description:	Ciomipramine Hy	drochloride 25mg 90c	t Capsules						Is this product to be shipped				No	
Andrew Income discourse.		Clomipramine Hydro	an alala si da					-	Is this product to be shipped	to customers on c	iry ice?		No	
Active Ingredient(s):		Ciomipramine Hydro	ocnioride					h Camtant fan t						
UBL for Additional Brades Information			and the second control of the second control					-	temperature excursion que	stions:	Customer Se			
URL for Additional Product Inform Address:	207 Kiley Drive	www.cadista.com	m/products/full-produc	<u>t-iist</u>		Address 2:			Name:		(800) 313-46			
	Salisbury						21801		Number: Group E-mail:		customer.s		diata aana	
City: Key Contact:	Jackie Emershaw	,				Jackie.Emershaw@ju		-	Group E-mail.		customer.s	ervicewca	uista.com	
Phone Number:	(410) 912-3722					(215) - 443 - 9646	JDI.COIII	a Special regul	lations for product in any s	totoo?			No	
		Antidonuncant			un.	(213) - 443 - 3040								
Product Therapeutic Classification	on:	Antidepressant						,	Special returns requirements	for this product?			No	
	ADDITI	ONAL PROPUST IN	FORMATION			PROPUST PERSON	IDTION INFORMATION	·						
	ADDITI	ONAL PRODUCT INF	FORMATION	<u> </u>		PRODUCT DESCR	IPTION INFORMATION	d. Store produc	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Only					Protect product (unit of sale	e) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	90 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			OILC.			Initial shelf life at launch (if	different):				Months
a product kit?		No				Strength:	25mg							
if yes, list NDCs of			FDA Approval Status			Ou chigan.				ORDER INFORM	IATION			
component parts						Dosage Form:	CAPSULES							
reverse numbered?		No				Doougo . o			Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 90			
latex-free?		Yes				Product Shape:	Capsule, Size 2		Box/Carton		(Write-in, e.g	g. 1 Box of 10) Vials)	
preservative-free?		No				oaaot onapo.			Ampule					
correctional institution block?		Yes				Product Color:	White / Yellow		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	US		Product Imprint:	C / 710		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for								Vial Liquid Multi		If Yes, how		ch package t	ype?
hospital scanning?			Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)? Yes					Vial Power Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Auth		thorized Generic, other		PHA	RMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB				Auth		thorized Generic, other n fields are not applicable	Rec. sell unit to		RMACY ORDER		nit to pharma	ncv:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Anafranil			Auth			Rec. sell unit to		RMACY ORDER	Rx billing ur	nit to pharma	acy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Anafranil			Auth			1 bott	o customer? tle of 90 capsules	RMACY ORDER	Rx billing ur		асу:	
			_Y CHAIN SECURITY ACT ((DSCSA) INFORMATIO					o customer? tle of 90 capsules	RMACY ORDER	Rx billing ur	Each	acy:	
			Y CHAIN SECURITY ACT ((DSCSA) INFORMATIO				1 bott	o customer? tle of 90 capsules	RMACY ORDER	Rx billing ur	Each Gram	acy:	
	and?:	DRUG SUPPL	Yes	(DSCSA) INFORMATIO	N			1 bott	o customer? tle of 90 capsules 1 Vial)	RMACY ORDER	Rx billing ur	Each Gram Milliliter	acy:	
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	DRUG SUPPL	Yes	GLN:	N [sectio 0359746000004 0359746		1 bott (Write-in, e.g. 1	o customer? tle of 90 capsules 1 Vial) ITEM Weight Lbs.	AND PACKING IN Dimensi Depth	Rx billing ur X IFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
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II. Generic Equivalent to What Bra Does supplier meet DSCSA definits 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/exception If yes, attach documentation fro Saleable Unit of Measure X Item/Each	and?: ition of manufactu s exclusive distrib ndexemption for p m FDA.	DRUG SUPPL rer? utor? roduct? GTIN	Yes No No No No No No	GLN: GCP: If yes, purche Provid	was origased dire	sectio 0359746000004 0359746 pinal product text from mfr? a manufacturer for reparations of the section of t	n fields are not applicable	1 bott (Write-in, e.g. 1 Item/Each: Box/Carton/Bu Inner Pack: Case:	o customer? tle of 90 capsules 1 Vial) ITEM Weight Lbs. 0.11 indle/ 2.16	AND PACKING IN Dimensi Depth 1.9	Rx billing ur X IFORMATION Ons (US msm Width 1.9 7.75	Each Gram Milliliter ts.) Height 4	Volume (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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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: 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?					