

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

Version 2021						Introduction ³	Туре:	New Item		X	Final Version			Date:	6/17	/2024
PRODUCT INFORMATION						SPECIAL HANDLING AND STOR			AGE REQUIREMENTS*							
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): ANDA 202280 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applicable:																
DUNS:	022490515										mperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Escital	opram Tablets								te in)					
Selling Unit NDC: UDI	59746-280-10		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3-597	746-280-10-9		Notes						
							l I				_					
Description: Escitalopram 10mg 1000ct Tablets										to customers on in			No No	-		
Active Ingredient(s): Is this product to be shipped to customers on dry icc								ily ice?		INO	_					
Active ingredient(s).						b. Contact for temperature excursion questions:										
URL for Additional Product Information: www.cadista.com/products/full-product-list									Name:				ervice			
Address:	790 Township Line Road				Address 2: Suite 325			Number:				(800) 313-4623				
City:					State:	PA	PA Zip: 19067 customer.service@cadista.com			Group E-mail:			customer.service@cadista.com			
Key Contact: Phone Number:				Email: Fax:	N/A	/ice@c	<u>adista.com</u>	a On a dall as mulations for most first in					No			
Product Therapeutic Classification	. ,			rax:	IN/A			c. Special regulations for product in any states? Special returns requirements for this product?				No			-	
Product Therapeutic Classification	m:	Anti-depressant								Special re	eturns requirement	s for this product?			INO	
	ADDIT	IONAL PRODUCT INF	FORMATION			PRODUCT	DESCR	RIPTION INFORMATION	d Store prod	luct (unit o	f sale) upright?				No	1
The product is?	7,55		Is the Product	Direct-Ship O	Inly	1 1102001	D_00.		d. otore proc		product (unit of sa	la) fram limbt?			No	1
a legend device?		No	Is the Product	Neither	Tilly			1000 count	e. Shelf life:	Protect p	product (unit or sa	ie) from light?			24	Months
if yes, enter class #		140	Orphan Drug Status	rtolatol		Size:		1000 Count	e. onen me.	Initial she	elf life at launch (i	if different):			24	Months
a product kit?		No				Ctuo month.		10mg								
if yes, list NDCs of			FDA Approval Status			Strength:			ORDER INFORMATION							
component parts						Dosage For	m:	TABLET								
reverse numbered?		No	All B							Unit of S			What is the		unit?	
co-licensed?		No Yes	Allergens Present					Oval, Biconvex, scorred			Bottle Box/Carton		1 Bottle of 1	g. 1 Box of 1	0 Viale)	
preservative-free?		No				Product Sha	ape:	Oval, Diconvex, Scored			Ampule		(vviite-iii, e.	g. I box of i	o viais)	
correctional institution block?		Yes				Book doors Oct		White			Glass		Minimum o	rder quantity	/?	Yes
opioid?		No				Product Col	or:				Tube					
Cannabinoid?		No	Country of Origin	US		Product Imp	rint.	"B" / "3" on one side			Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for							"C" on the back			Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered u		V			Vial Powder Sql			12 Each					
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)?				Yes				Vial Power Multi Other: Write In			Inner/Carton/Pack Case					
			FOR GENERIC DRUG PR	ODUCTS							Other: White iii			Ousc		
			TON OZNZNIO DNOOTN	5555.5						l.						
					Au	thorized Generic	*If Au	thorized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB					sectio	on fields are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:				acv:					
II. Generic Equivalent to What Bra	and?:	Lexapro®		_					1 Bottle of 1000 tablets				X Each			
·									(Write-in, e.g. 1 Vial) Gram							
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION									Milliliter		
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0359746000004						ITEM	AND PACKING I	JEORMATIO	N							
Is product exempt from DSCSA?		ilei t	Yes No	+	GLN:	0359746000004					IIEW	PACKING II	W OKWATIO	N		
·					GCP:	0359746						Dimensi	ons (US msn	nte \	Valuma	Calaabla#
If yes, select exemption: Other exemption - Write in:					GCP:	0359746					Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If ves. was o	riginal product pur	chased	1	Item/Each:			1			<u> </u>	
Is product sold by manufacturer's	s exclusive distrib	utor?	No		direct from n						0.47	2.60	2.60	4.20	28.39	1
Has FDA granted waiver/exceptio		roduct?	No		Provide sour	ce manufacturer fo	or repa	ckaged product	Box/Carton/E	Bundle/					0.00	
If yes, attach documentation fro	m FDA.								Inner Pack:						0.00	
		CTII	N AND HIBCC PRODUCT IF	JEODMATION					Case:		6.60	11.00	8.50	6.50	607.75	12
		GIII	N AND HIBCC PRODUCT IF	NFORMATION					Pallet:							
Saleable Unit of Measure		Saleable Quantity	HIBCC		GT	N-14		Unit of Use GTIN-14	l'anet.						0.00	
X Item/Each		1				59746280109						1				
Box/Carton/Bundle/Inner Pack						COST INFORMATION WHOLESALER USE ONLY:						_Y:				
X Case		12			403	59746280107										
Pallet									Regular Cost				Vendor #:			
									Invoice Cost	(WAC) (\$)		\$120.00	Whsl. Code Fineline Co			
					-				As of date:	ı			i illeline Co	ue.		
									, 10 0, date.	Į.			1			
													<u></u>			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE	INSEF	RT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and	BARCODE.					
*Please provide any additional inf		_						nated Dron Shin Only								



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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?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive Inorganic Oxidizer						
Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	Inorganic Oxidizer Steroid/Androgen Contact Hazard						
boes the product label bear a OATTOP to warning:	Ornaci Tazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?							
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number							
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry? Website URL:						
e. Inhalation Hazard?	Website ORL.						
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? No	REMS:						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below) Limited Quantity	Provider Name: DEA #: Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry:						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:						
	Comments						
Is the Product Controlled Substance 2	RETURN INSTRUCTIONS						
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	KETORI NOTIONS						
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:	Consider outletions or returns continued for this						
Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:						
- INIGCLELAT							



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method fo	r Designated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:						
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:						
F	Name: Phone:	Ships regular ground for 3-10 days receipt:						
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:		Overnight receipt available:						
Drop Ship service fee billed with each order:		PO Receipt cut off time:						
Drop Ship miscellaneous fees billed: Comments:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:						
Other Data Infor	rmation Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?						
Mis	scellaneous Notes:							
		ADDITIONAL INFORMATION						
		Is product order for scheduled patient procedure? Is product order for restocking purposes?						