

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

Version 2021						Introduction Type	e: Post Launch Cha	ange	x	Final Version			Date:	7/12/	2021	
			PRODUCT INFORMAT	TION						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/ANDA/BLA (drug); PMA/510(k)(med device): 077563						7.000.00	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				Controlled Room -		and 25 C (68	° – 77° F)		
Medical Device Class, if applical		iii uu ru(ii)(iiiuu uu ri		-					101116	orataro rtango				,		
DUNS:	022490515				I				Other	Temperature Range R	equirement					
Proprietary Name (If Applicable) a		me: Cyclob	penzaprine HCl Tablets		1					(write in)	equilement					
Selling Unit NDC:	59746-177-06	inc. Oyoloc	Unit of Use NDC:			UPC: 3	-59746-177-06-5		Notes							
UDI	001 10 111 00		CVX Code:			MVX Code:			110100	•						
-	0 11		_									_				
Description:	Cyclobenzaprine	Hydrochloride 10mg 1	100ct lablet							product to be shipped				No		
Anthor In our disputation		Cyclobenzaprine Hy	ماداد ما ما محادد						Is this	s product to be shipped	to customers on d	ry ice?		No		
Active Ingredient(s):		Cyclobenzaprine Hy	yarocnioriae						h Cantast (as tames							
URL for Additional Product Inform			and the second control of the second control							erature excursion que	stions:	Customes C				
Address:	207 Kiley Drive	www.cadista.com/products/full-product-list			1	Address 2:			Name: Number:			Customer Service (800) 313-4623				
City:	Salisbury				State:	MD Zip: 21801			Group E-mail:			customer.service@cadista.com				
Key Contact:	Jackie Emershaw	now.				Jackie.Emershaw@jubl.com			Giou	p E-IIIaii.		customer.	ser vice wca	iuista.com		
Phone Number:	(410) 912-3722					(215) - 443 - 9646	/@jubi.com		c. Special regulations for product in any states?					No		
Product Therapeutic Classification		Analgesic Muscle R	Polovont			(210) 440 3040				ial returns requirements						
Product Therapeutic Classification	on:	Arialgesic Muscle N	Neidadiii						Speci	iai returns requirements	ior tris product?			No		
	ADDITI	ONAL PRODUCT INI	EORMATION -			BRODUC T DE	SCRIPTION INFORMATION	ON	d Ctore mandaret (it of ools)int :0				Nie		
	ADDIII	SNAL PRODUCT IN				PRODUCT DE	SCRIP HON INFORMATIO	ON	d. Store product (un					No		
The product is?			Is the Product	Direct-Ship C	Only					ect product (unit of sa	e) from light?			No		
a legend device?		No	Is the Product	Neither		Size:	100 count	1	e. Shelf life:					24	Months	
if yes, enter class #			Orphan Drug Status						Initia	l shelf life at launch (i	different):				Months	
a product kit?		No				Strength:	10mg									
if yes, list NDCs of			FDA Approval Status								ORDER INFORM	ATION				
component parts						Dosage Form:	TABLETS					Mm	NDO III			
reverse numbered? co-licensed?		No							Unit	of Sale Bottle		1 bottle of 1	NDC selling	unit?		
latex-free?		No	Allergens Present				Round		^	Box/Carton				0 \ /i.e.le.\		
preservative-free?		Yes				Product Shape	: Round			Ampule		(vviite-iri, e.	g. 1 Box of 1	o viais)		
correctional institution block?		No					Yellow			Glass		Minimum o	der quantity		Yes	
opioid?		Yes				Product Color:	reliow			Tube		William O	uer quaritity	•	res	
Cannabinoid?		No	Country of Origin	US			TL 177			Vial Liquid Sql						
If Unit Dose, is item bar coded to u	unit doce for	No	Country of Origin	00		Product Imprir	it:			Vial Liquid Multi		If Yes how	many of whi	ch package	tyne?	
hospital scanning?	unit dose for		Is this product covered u	nder the						Vial Powder Sql		48	Each	cii package	ype:	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	TAA)?	Yes					Vial Power Multi			Inner/Carton	/Pack		
II Olik Bose, indicate NBO here.				,	103					Other: Write In			Case	/ dok		
			FOR GENERIC DRUG PRO	DDUCTS				-								
Authorized Generic "If Authorized Generic, other									PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	coation fields are not applicable							cable	Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Flexeril							1 bottle of 100 tablets				X Each					
									(Write-in, e.g. 1 Vial)				Gram			
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	RMATION				(,,				Milliliter			
Does supplier meet DSCSA defini		rer?	Yes		GLN:	0359746000004				ITEM	AND PACKING IN	FORMATIO				
Is product exempt from DSCSA?			No													
			140	_								// 10	ıts.)	Volume	Saleable #	
If yes, select exemption:			110		GCP:	0359746				Weight I he	Dimensi	ons (US msn		(Cube)	Pieces	
Other exemption - Write in:										Weight Lbs.	Dimensi Depth	Width	Height		1	
Other exemption - Write in: Is product repackaged?			No		If yes, was or	riginal product			Item/Each:	Weight Lbs.			Height 4.75	27.36		
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's			No No		If yes, was or	riginal product irect from mfr?				0.4	Depth	Width		27.36		
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	on/exemption for p		No		If yes, was or	riginal product	repackaged product		Box/Carton/Bundle/	0.4	Depth	Width		27.36 0.00		
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	on/exemption for p		No No		If yes, was or	riginal product irect from mfr?	repackaged product		Box/Carton/Bundle/ Inner Pack:	0.4	Depth	Width				
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	on/exemption for p	roduct?	No No No		If yes, was or	riginal product irect from mfr?	repackaged product		Box/Carton/Bundle/	0.4	Depth	Width			48	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	on/exemption for p	roduct?	No No	IFORMATION	If yes, was or	riginal product irect from mfr?	repackaged product		Box/Carton/Bundle/ Inner Pack: Case:	0.4	Depth 2.4	Width 2.4	4.75	0.00	48	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	on/exemption for pa om FDA.	oduct?	No No No N AND HIBCC PRODUCT IN	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for			Box/Carton/Bundle/ Inner Pack:	0.4	Depth 2.4	Width 2.4	4.75	0.00	48	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	on/exemption for pa om FDA.	roduct?	No No No	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for	repackaged product Unit of Use GTIN-1		Box/Carton/Bundle/ Inner Pack: Case:	0.4	Depth 2.4	Width 2.4	4.75	0.00	48	
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 Item/Each	on/exemption for pa om FDA.	oduct?	No No No N AND HIBCC PRODUCT IN	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for			Box/Carton/Bundle/ Inner Pack: Case: Pallet:	5.16	Depth 2.4	Width 2.4 7.5	4.75 5.13	0.00 394.37 0.00		
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	on/exemption for pa om FDA.	GTII	No No No N AND HIBCC PRODUCT IN	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for N-14 59746177065			Box/Carton/Bundle/ Inner Pack: Case: Pallet:	0.4	Depth 2.4	Width 2.4 7.5	4.75 5.13	0.00		
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 Box/Carton/Bundle/Inner Pack	on/exemption for pa om FDA.	oduct?	No No No N AND HIBCC PRODUCT IN	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for		14	Box/Carton/Bundle/ Inner Pack: Case: Pallet:	5.16	Depth 2.4	Width 2.4 7.5	4.75 5.13	0.00 394.37 0.00		
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	on/exemption for pa om FDA.	GTII	No No No N AND HIBCC PRODUCT IN	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for N-14 59746177065		14	Box/Carton/Bundle/ Inner Pack: Case: Pallet:	0.4 5.16 OST INFORMATION	Depth 2.4	Width 2.4 7.5	4.75 5.13 WHOLESAL	0.00 394.37 0.00		
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	on/exemption for pa om FDA.	GTII	No No No N AND HIBCC PRODUCT IN	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for N-14 59746177065		14	Box/Carton/Bundle/ Inner Pack: Case: Pallet:	0.4 5.16 OST INFORMATION	2.4 10.25	Width 2.4 7.5 Vendor #:	4.75 5.13 WHOLESALI	0.00 394.37 0.00		
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	on/exemption for pa om FDA.	GTII	No No No N AND HIBCC PRODUCT IN	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for N-14 59746177065		14	Box/Carton/Bundle/ Inner Pack: Case: Pallet:	0.4 5.16 OST INFORMATION	2.4 10.25	Width 2.4 7.5 Vendor #: Whsl. Code	4.75 5.13 WHOLESALI	0.00 394.37 0.00		
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	on/exemption for pa om FDA.	GTII	No No No N AND HIBCC PRODUCT IN	IFORMATION	If yes, was or purchased di Provide sour	riginal product irect from mfr? ce manufacturer for N-14 59746177065		14	Box/Carton/Bundle/ Inner Pack: Case: Pallet: Ci Regular Cost Invoice Cost (WAC)	0.4 5.16 OST INFORMATION	2.4 10.25	Width 2.4 7.5 Vendor #: Whsl. Code	4.75 5.13 WHOLESALI	0.00 394.37 0.00		
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	on/exemption for pa om FDA.	GTIII	No No No No No NAND HIBCC PRODUCT IN		If yes, was on purchased di Provide sour	riginal product frect from mfr? cce manufacturer for N-14 59746177063	Unit of Use GTIN-1	114	Box/Carton/Bundle/ Inner Pack: Case: Pallet: C Regular Cost Invoice Cost (WAC) As of date:	0.4 5.16 OST INFORMATION (\$)	2.4 10.25	Width 2.4 7.5 Vendor #: Whsl. Code	4.75 5.13 WHOLESALI	0.00 394.37 0.00		
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 Box/Carton/Bundle/Inner Pack X Case	on/exemption for pa om FDA.	GTIII	No No No N AND HIBCC PRODUCT IN		If yes, was on purchased di Provide sour	riginal product frect from mfr? cce manufacturer for N-14 59746177063	Unit of Use GTIN-1	114	Box/Carton/Bundle/ Inner Pack: Case: Pallet: C Regular Cost Invoice Cost (WAC) As of date:	0.4 5.16 OST INFORMATION (\$)	2.4 10.25	Width 2.4 7.5 Vendor #: Whsl. Code	4.75 5.13 WHOLESALI	0.00 394.37 0.00		



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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?						