

Standard Pharmaceutical Product Information (Rx Product Only)

					Introducti	on Type:	Post Launch Change	X	Final Version			Date:	2/12	/2021		
			PRODUCT INFORMATION						SPECIAL HANDLI	ING AND STO	RAGE REQU	JIREMENTS	*			
Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.								
Application Number for ND	ber for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A77563							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° I								
DUNS:	022490515						Other Temperature Range Requirement									
Proprietary Name (If Applicable) and Established Name: Cyclobenzaprine HCL Tablets									rite in)	·]		
Selling Unit NDC:																
UDI			CVX Code: MVX Code:				Is this product to be shipped to customers on ice? No					-				
Description: Cyclobenzaprine HCL 10mg Tablets 100ct									Is this product to be shipped to customers on dry ice? No							
Active Ingredient(s).																
Active Ingredient(s): Cyclobenzaprine								b. Contact for tempera Name:	iture excursion ques		Customer Support					
URL for Additional Product Information: www.cadista.com								Number:			(800) 313-4623					
Address:	207 Kiley Drive		Address 2:				Group E-mail:									
City:	Salisbury		State: MD			Zip:	21801									
Key Contact:	Jackie Emershaw (410) 912-3722						Emershaw@cadista.com		c. Special regulations for product in any states?				No No			
Phone Number: Product Therapeutic Classific	. ,	Analgesic Muscle Relaxa	unt .	Fax: (215) 443-9646				Special returns requirements for this product? No								
Froduct Therapeutic Classifi	cation.	Analyesic Muscle Relaxa	III.					d Store product (unit	of sale) unright?				No			
ADDITIONA	L PRODUCT INFORM	IATION			PRODUCT DESC	CRIPTION INFOR	MATION	d. Store product (unit of sale) upright? Protect product (unit of sale) from light? No								
Is the Product								e. Shelf life:				24 Months				
a legend device?		Yes							nelf life at launch (if	different):			24	Months		
reverse numbered?		No	Size:		100ct	100ct		I amiliar cricii inic ar manicii (ii amicroni).								
co-licensed?				Strength:	10mg				C	RDER INFOR	MATION					
Is the Product				Oli Cligili.	Tollig											
Is the Product			Dosage Form	n: TAB			Unit of S	-		What is the 1 case of 48		unit?				
								X	Bottle Box/Carton		(Write-in, e.g		0 Vials)			
If Unit Dose, is item bar coded to unit dose for hospital scanning?				Product Shap	Davis.	4			Ampule		(**************************************	g. 1 Box or 1	o vidio,			
If Unit Dose NDC, indicate NI	DC here:			Froduct Shap	pe: Round	u		Glass Minimum order quantity? Yes								
Product Color: Yellow								Tube								
Country of Origin									Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of whi	ich nackage	tyne?		
Is this product covered under the Trade Agreements Act (TAA)? Yes Product Imprint: debossed TL-177								Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql 48 Each								
100							Vial Power Multi Inner/Carton/Pack									
									Other: Write In	_		Case				
			FOR GENERIC DRUG PRODUC	CTS												
				Auth	norized Generic	*If Authorize	ed Generic, other section	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	AB			fields are not applicable								Rx billing unit to pharmacy:				
II. Generic Equivalent to Wha		Flexeril®									Each					
								(Write-in, e.g. 1 Vial)								
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCS	SA) INFORMATION								Milliliter				
Does supplier meet DSCSA of	definition of manufact	turor?	Yes	GLN:	359746000004	4			ITEM AN	ND PACKING	INFORMATI	ON				
Is product exempt from DSC			100	GLIV.	3337 4000000	•		TI LIM AND FACKING INTOKINATION								
If yes, select exemption:									Weight Lbs.	Dimen	sions (US m	smts.)	Volume	# Pieces:		
Other exemption - Write in:							I		weight Lbs.	Depth	Height	Width	(Cube)	# Fieces.		
Is product repackaged?			No No	If Yes, was origing from mfr?	nal product purc	hased direct		Item:	0.09	1.9	4	1.9	14.44	1		
Is product sold by manufactu Has FDA granted waiver/exce			No	If yes, attach doo	cumentation from	n FDA		Box/Carton/Bundle/								
nao i zai granica marronaxo.	option, oxomption for			,00, anaon ao		27.0		Inner Pack:					0			
			GTIN PRODUCT INFORMATION	ON				Case:	5.14	15.5	5.25	11.75	956.16	48		
			Salea						3.14	10.0	3.23	11.75	330.10	40		
Serialized?	Yes	x	Level Unit Item	nit x 2D	Linea	Quantity 1	GTIN-14 00359746177065 40359746177063	Pallet:					0			
If not, when?	res			2D 2D	Linear	-		UPC:	Case:					1		
Items aggregated?					Linear	48		Carton:								
00 0			Pallet	2D	Linear											
	2D Linear							COST INFORMATION WHOLESALER USE ONLY:								
				2D	Linear							i				
	2D Linear 2D Lin					Regular Cost			Vendor #: Whsl. Code #:							
		الــــا			Linear			Invoice Cost (WAC) (\$) Federal Excise Tax Pe		\$7.10	Fineline Code					
								As of date:		1						
											•					
			tach copy of SAFETY DATA SH	EET (SDS) or non haz												
*Please provide any addition	al information on pag	je 2.			See new p. 3	for Designated D	Prop Ship Only.	Signatu	re:							



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? No RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS Program Manager Name: Limited Quantity Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: SP# PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? Nο Controlled by State(s)? Registry: ARCOS Reportable? Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) RETURN INSTRUCTIONS If yes, indicate which: (410) 912-3722 Is it a scheduled listed chemical product?: Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: Yes www.cadista.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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 Yes	Purchase order daily receipt cut off time by supplier Cut off time:						
b. Autofax C. Fax Yes Fax Number: Yes Fax Number: Phone No.: Supplier Web Site only Site Address:	Shipping lead time of PO: Hours Days						
e. Supplier Web Site only Minimum Order Quantity: 48 Supplier's Customer Service Number: (410) 912-3722 Contracted 3PL company / contact #: Name: Phone:	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:	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, 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: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # 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?						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						