

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

Version 2021						Introduction Ty	/pe:	New Item		X Final Version			Date:	5/3/2	2023
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Jubilant Cadista F	Pharmaceuticals Inc.				Application	on:	ANDA	a. Temperature –	Indicate the USP tempe	rature range for t	nis product.			
Application Number for NDA/ANI			ce):	ANE	DA 211013					nperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:															
DUNS:	022490515			1					Oth	ner Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Nitrofu	urantoin Capsules							(write in)	•				
Selling Unit NDC:	59746-762-01		Unit of Use NDC:				3-59746-762-	-01-8	No	tes					
UDI			CVX Code:			MVX Code:									
Description: Nitrofurantoin 100mg 100ct Capsules Is this product to be shipped to customers on ice? No															
										his product to be shipped				No	
Active Ingredient(s):		Nitrofurantoin Mond	ohydrate-Macrocrystals, 75m	g;25mg								•			
									b. Contact for tem	perature excursion que	estions:				
URL for Additional Product Inform		www.cadista.co	m/products/full-product	<u>-list</u>					Na			Customer Se			
Address:	207 Kiley Drive					Address 2:				mber:		(800) 313-46			
City:	Salisbury				State:		Zip : 2180		Gre	oup E-mail:		customer.	service@ca	dista.com	
Key Contact:	Customer Service	•			Email:	customer.servic	ce@cadista.	<u>.com</u>							1
Phone Number:	(800) 313-4623				Fax:	N/A				ions for product in any				No	
Product Therapeutic Classification	1:	Antibacterial agent							Spe	ecial returns requirement	s for this product?			No	
	ADDITI	ONAL PRODUCT IN	IFORMATION			PRODUCT D	ESCRIPTION	INFORMATION	d. Store product (unit of sale) upright?				No	ļ
The product is?			Is the Product	Direct-Ship Or	nly			_	Pro	otect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100 cc	ount	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.			Init	ial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	100mg	g							
if yes, list NDCs of			FDA Approval Status								ORDER INFORM	IATION			
component parts		1				Dosage Form:	: CAPS	OLE				\A/l4 :- 4h	NDC aallina	:42	
reverse numbered?		No	Allaumana Duagant							it of Sale X Bottle		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Cizo 1	Capsule		X Bottle Box/Carton		1 Case of 24	g. 1 Box of 10	\ \/iolo\	
preservative-free?		No				Product Shap	e:	Capsule		Ampule		(vviite-iii, e.	y. 1 box of 10	viais)	
correctional institution block?		Yes					Black/	Yellow		Glass		Minimum or	der auantity	2	Yes
opioid?		No				Product Color	r: Diacio	TOIIOW		Tube			uci quantity	•	103
Cannabinoid?		No	Country of Origin	US			102'			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for	1.14	,			Product Impri	int:			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	No					Vial Power Multi			Inner/Carton	/Pack	
			_							Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS								1			
												-			
					Au			d Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields	are not applicable	Rec. sell unit to c	ustomer?		Rx billing u	nit to pharma	icy:	
II. Generic Equivalent to What Bra	nd?:	Macrobid®							1 Bottle	of 100 tablets		Х	Each	-	
									(Write-in, e.g. 1 Vi	ial)			Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT (DSCSA) INFORI	MATION								Milliliter		
				_											
Does supplier meet DSCSA definit	tion of manufactur	rer?	Yes	_	GLN:	0359746000004				ITEN	AND PACKING I	NFORMATION	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:	0359746				Weight Lbs.		ons (US msm	•	Volume	Saleable #
Other exemption - Write in:										TTOIGHT EDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purch	hased		Item/Each:	0.21	2.22	2.22	4.53	22.33	1
Is product sold by manufacturer's			No	→	direct from m				l - 12 · 15 ·						
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer for	repackaged	product	Box/Carton/Bund	le/				0.00	
If yes, attach documentation from	n FDA.								Inner Pack:						
		CT	IN AND HIBCC PRODUCT II	JEORMATION					Case:	6.18	13.86	9.45	7.51	983.64	24
		GII	IN AND HIBCC PRODUCT II	NFORMATION					Pallet:						
Saleable Unit of Measure	9	Saleable Quantity	HIBCC		GTII	N-14	Unit	of Use GTIN-14	railet.					0.00	
X Item/Each		1	TIIDCC			59746762018	Offic	01 036 01114-14							
Box/Carton/Bundle/Inner Pack										COST INFORMATION			WHOLESALE	R USE ONL	Y:
X Case		24			403	59746762016									
Pallet									Regular Cost			Vendor #:			
	Ī								Invoice Cost (WA	C) (\$)	\$156.44	Whsl. Code	#:		
	I											Fineline Co	de:		
	I								As of date:]			
	1														
1									ļ			L			
			Attach copy of SAFETY DA	TA SHEET (SDS	S) or non haza										
*Please provide any additional info						See new p. 3 for D			C:-	ınature:					



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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? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification						
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard						
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	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:						
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
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 c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:						
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
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 Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: PROVIDENTIAL PROPOSED STATE OF THE P						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry:						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No CLASS OF TRADE RESTRICTION:	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 Yes							
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	EOUS 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 f	or 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: Supplier's Customer Service Number: Contracted 3PL company / contact #:	Fax Number: Fax Number: Phone No.: Site Address: Name: Phone:	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 Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order	r:	Overnight receipt available:
Drop Ship service fee billed with each order Drop Ship miscellaneous fees billed: Comments:		PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Clas	ss of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail ph Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician Restricted from US territories? (explain in co		Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Info	ormation 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?
	liscellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?