

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

Version 2021							Гуре:	Post Launch Change		x Final Version			Date:	7/12/	2021
			PRODUCT INFORMAT	TION						SPECIAL HANI	DLING AND STOR	RAGE 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/B.4 (drug): PMA/510(k)(med device): 20354 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)															
Medical Device Class, if applicable:															
DUNS:	022490515								1	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Irbe	sartan Tablets						1	(write in)					
Selling Unit NDC:	59746-448-30		Unit of Use NDC:			UPC:	3-5974	46-448-30-1		Notes					
UDI			CVX Code:			MVX Code:									
Description: Irbesartan 150mg 30 Tablets									il ı	s this product to be shipped	to customers on i	ce?		No	
bescription.	inboodituin roomig	oo rabioto								s this product to be shipped				No	
Active Ingredient(s):		Irbesartan										,			
5 (,,	b. Contact for t	b. Contact for temperature excursion questions:													
URL for Additional Product Inform	luct Information: www.cadista.com/products/full-product-list							Name: Customer Service							
Address:	207 Kiley Drive					Address 2:			Number:			(800) 313-4623			
City:	Salisbury				State:	MD Zip : 21801			(customer.service@cadista.com					
Key Contact:	Jackie Emershaw				Email:	Jackie.Emershaw@jubl.com			4						
Phone Number:	(410) 912-3722				Fax:	(215) - 443 - 9646			c. Special regu	No					
Product Therapeutic Classification	Antihypertensive									Special returns requirement	s for this product?			No	
	4 B B I T I		NIEGO I I EIGH												
	ADDITI	ONAL PRODUCT	INFORMATION			PRODUCTI	DESCR	IPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only					Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:		30 count	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						'	nitial shelf life at launch (i	f different):				Months
a product kit?	No				Strength: 150mg										
if yes, list NDCs of			FDA Approval Status					TADLET			ORDER INFORM	IATION			
component parts reverse numbered?		No				Dosage Forn	n:	TABLET		Jnit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present						ll r	X Bottle		1 bottle of 3		unit:	
latex-free?		Yes	Allergens Fresent					Oval, Biconvex		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		No				Product Sha	ipe:	Oval, Bibbillox		Ampule		(**************************************	g. 1 Dox 01 1	o viaio,	
correctional institution block?		Yes				Burnet Cal		White		Glass		Minimum o	rder quantity	?	Yes
opioid?		No				Product Cole	or:			Tube					
Cannabinoid?		No	Country of Origin	IN		Product Imp	rint.	C / 448		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					Froduct IIIIp	TIIIL.			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u							Vial Powder Sql		48	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (ГАА)?	No					Vial Power Multi			Inner/Carton	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS											
												/ BU			
					Au	uthorized Generic		thorized Generic, other		PH.	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:			section fields are not applicable			Rec. sell unit to	Rx billing unit to pharmacy:								
II. Generic Equivalent to What Brand?: Avapro							1 bottle of 30 tablets			X Each					
		P.D.I.O. 011D	DI V 011111 0501 DITV 105 ((Write-in, e.g. 1	Vial)			Gram		
		DRUG SUP	PLY CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION				.				Milliliter		
Does supplier meet DSCSA defin	ition of manufactur	ror2	Yes		GLN:	8902805000006				ITEM	AND PACKING II	NEODMATIO	NI .		
Is product exempt from DSCSA?		1011	No		JLN.	3302003000000				TI EWI	AND I ACKING II	OKWIATIO	-		
•			110			0050740			1		Dimensi	/IIC	-4- \		
If yes, select exemption: Other exemption - Write in:					GCP:	0359746				Weight Lbs.	Dimensi	ions (US msr Width	nts.) Height	Volume (Cube)	Saleable # Pieces
-			No		If was was a	riginal product			Item/Each:		Depth	wiath	neight	(Cube)	rieces
Is product repackaged? Is product sold by manufacturer's	s exclusive distrib	utor?	No	-		riginal product irect from mfr?			nemy Each.	0.06	1.9	1.9	4	14.44	1
Has FDA granted waiver/exception			No		-	ce manufacturer fo	or renac	ckaged product	Box/Carton/Bu	ndle/					
If yes, attach documentation fro				_				- I Jan product	Inner Pack:					0.00	
•									Case:	3.74	14.25	10.71	4.72	720.35	48
		G	TIN AND HIBCC PRODUCT IN	IFORMATION						3.74	14.25	10.71	4.72	720.35	40
									Pallet:					0.00	
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14	_	Unit of Use GTIN-14						0.00	
X Item/Each	1 00359746448301							0005 11/505							
Box/Carton/Bundle/Inner Pack					740440000			COST INFORMATION			WHOLESALER USE ONLY:				
X Case		48			403	59746448309			Damide Co.			Vendor #:			
Pallet							-		Regular Cost	(AC) (C)	644.00		ш.		
									Invoice Cost (W	IAC) (4)	\$11.09	Whsl. Code Fineline Co			
									As of date:						
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSER	RT, LABEL AND PHOTO OF F	PRODUCT PACKAG	SING and BARCODE.					
İ	formation on nage	_		,				nated Dron Shin Only		Signature:					



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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: 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?						