



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final VersionDate: 

PRODUCT INFORMATION	
Company Name:	Jubilant Cadista Pharmaceuticals Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	203534
DUNS:	22490515
Proprietary Name (If Applicable) and Established Name:	Irbesartan
Selling Unit NDC:	59746-0449-30
Individual Unit NDC:	
UPC:	359746449308
UDI	
CVX Code:	
MVX Code:	
Description:	Irbesartan 300mg Tablet 30
Active Ingredient(s):	Irbesartan USP
URL for Additional Product Information:	
Address:	207 Kiley Drive
City:	Salisbury
Key Contact:	Jackie Emershaw
Phone Number:	(410) 912-3722
Product Therapeutic Classification:	Antihypertensive

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
<b>b. Contact for temperature excursion questions:</b>	
Name:	Customer Service
Number:	(800) 313-4623
Group E-mail:	
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="text" value="Yes"/>
reverse numbered?	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>
Is the Product... Direct-Ship Only?	<input type="text" value="Direct-Ship Only"/>
Is the Product... Direct-Ship Only?	<input type="text" value="Direct-Ship Only"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>
If Unit Dose NDC, indicate NDC here:	<input type="text" value=""/>
Country of Origin	<input type="text" value=""/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	30ct
Strength:	300mg
Dosage Form:	Tablets
Product Shape:	Oval
Product Color:	White to Off-White
Product Imprint:	449, 'C'

ORDER INFORMATION	
<b>Unit of Sale</b>	<b>What is the NDC selling unit?</b>
<input checked="" type="checkbox"/> Bottle	1 case of 48 bottles
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	
	<b>Minimum order quantity?</b> <input type="text" value="Yes"/>
	<b>If Yes, how many of which package type?</b>
	<input type="text" value="48"/> Each
	<input type="text" value=""/>
	<input type="text" value=""/>
	<input type="text" value=""/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/>
II. Generic Equivalent to What Brand?:	<input type="text" value="Avapro®"/>
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value=""/>	<input type="text" value=""/>
(Write-in, e.g. 1 Vial)	Each
	Gram
	Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text" value=""/>
Other exemption - Write in:	<input type="text" value=""/>
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value=""/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
GLN:	<input type="text" value="8902805000006"/>
If Yes, was original product purchased direct from mfr?	<input type="text" value=""/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.09	1.87	3.77	1.87	13.18	
Case:	6.83	15.24	5.51	11.50	965.68	48
Pallet:					0	
UPC:						
Case:						
Carton:						

GTIN PRODUCT INFORMATION			
Serialized?	Yes		
If not, when?	<input type="text" value=""/>		
Items aggregated?	<input type="text" value=""/>		
Level	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Item	<input type="checkbox"/>	1	00359746449308
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>		
<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	48	40359746449306
<input type="checkbox"/> Pallet	<input type="checkbox"/>		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$ 13.34	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	<input type="text" value=""/>		

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 |
| b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  |    |
| Is the product a CA Prop 65 carcinogen?  | No |
| Is the product a CA Prop 65 reproductive toxicant?   | No |
| Does the product label bear a CA Prop 65 warning?  | No |
| c. Contact Hazard?   | No |
| d. Does this product require special clean-up instructions?<br>(If yes, attach SDS with special instructions.) | No |
| e. Does the product contain DEHP?  | No |
| Is this product regulated for shipment by DOT or IATA?<br>(if yes, answer a-e below and provide SDS)           | No |

- |                             |    |
|-----------------------------|----|
| a. UN/Identification Number |    |
| b. Proper Shipping Name     |    |
| c. DOT Hazard Class         |    |
| d. Packing Group            |    |
| e. Inhalation Hazard?       | No |

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger  
 Cargo  
 Passenger & Cargo

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)  
 Special Permit; DOT-SP  
 Special Provision (listed in Column 7 of 49 CFR 172.101);  
 SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- |   |    |
|---|----|
| Controlled Substance?                       | No |
| Controlled by State(s)?                     | No |
| ARCOS Reportable?                           | No |
| Schedule No. (inc. N for non-narcotic)      |    |
| Controlled Substance Code                   |    |
| Listed Chemical (List I or II)              | No |
| If yes, indicate which:                     |    |
| Is it a scheduled listed chemical product?: |    |

### CLASS OF TRADE RESTRICTION:

- |   |     |
|---|-----|
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | Yes |
| Restricted to retail pharmacy only:   | No  |
| Restricted to hospital, clinics, and physician offices only:                                    | No  |
| Restricted from US territories? (explain in comments)   | No  |

Comments:

### SDS Hazard Classification

- |   |  |
|---|--|
| <input type="checkbox"/> Organic<br><input type="checkbox"/> Inorganic<br><input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Corrosive<br><input type="checkbox"/> Oxidizer<br><input type="checkbox"/> Contact Hazard |
|---|--|

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No  
 If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

REMS: No

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:  DEA #:

PCPDP #:

NPI #:

Comments:

Registry:

Registry Program Contact Name:  Phone:

Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: Yes

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 and/or Image of Product Barcode:

**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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<input style="width: 100%; height: 80px;" type="text"/>	