



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

Version 2021 Introduction Type: Post Launch Change Final Version Date: 6/9/2023

PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 201170
Medical Device Class, if applicable: _____
DUNS: 022490515
Proprietary Name (If Applicable) and Established Name: Losartan Potassium Tablets
Selling Unit NDC: 59746-334-10 **Unit of Use NDC:** _____ **UPC:** 3-59746-334-10-9
UDI _____ **CVX Code:** _____ **MXV Code:** _____
Description: Losartan Potassium 50mg 1000ct Tablet
Active Ingredient(s): Losartan Potassium
URL for Additional Product Information: www.cadista.com/products/full-product-list
Address: 207 Kiley Drive **Address 2:** _____
City: Salisbury **State:** MD **Zip:** 21801
Key Contact: Customer Service **Email:** customer.service@cadista.com
Phone Number: (800) 313-4623 **Fax:** N/A
Product Therapeutic Classification: Antihypertensive

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range
Other Temperature Range Requirement (write in) _____
Notes _____
 Is this product to be shipped to customers on ice? No
 Is this product to be shipped to customers on dry ice? No
b. Contact for temperature excursion questions:
Name: Customer Service
Number: (800) 313-4623
Group E-mail: customer.service@cadista.com
c. Special regulations for product in any states? No
 Special returns requirements for this product? No
d. Store product (unit of sale) upright? No
 Protect product (unit of sale) from light? No
e. Shelf life: 24 Months
 Initial shelf life at launch (if different): _____ Months

ADDITIONAL PRODUCT INFORMATION

The product is?
 a legend device? No
 if yes, enter class # _____
 a product kit? No
 if yes, list NDCs of component parts reverse numbered? _____
 co-licensed? No
 latex-free? Yes
 preservative-free? No
 correctional institution block? Yes
 opioid? No
 Cannabinoid? No
 If Unit Dose, is item bar coded to unit dose for hospital scanning? _____
 If Unit Dose, indicate NDC here: _____

Is the Product... Direct-Ship Only _____
Is the Product... Neither _____
Orphan Drug Status _____
FDA Approval Status _____
Allergens Present _____
Country of Origin
 Is this product covered under the Trade Agreements Act (TAA)? Yes

PRODUCT DESCRIPTION INFORMATION

Size: 1000 count
Strength: 50mg
Dosage Form: TABLETS
Product Shape: Oval, Scored
Product Color: Green
Product Imprint: C / 334

ORDER INFORMATION

Unit of Sale
 Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Power Multi
 Other: Write In _____

What is the NDC selling unit?

 (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?
 Each
 Inner/ Carton/Pack
 Case

FOR GENERIC DRUG PRODUCTS

Authorized Generic *If Authorized Generic, other section fields are not applicable
I. Orange Book Rating:
II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
Is product exempt from DSCSA? No
 If yes, select exemption:
 Other exemption - Write in: _____
Is product repackaged? No
Is product sold by manufacturer's exclusive distributor? No
Has FDA granted waiver/exception/exemption for product? No
 If yes, attach documentation from FDA.
GLN: 0359746000004
GCP: 0359746
 If yes, was original product purchased direct from mfr? _____
 Provide source manufacturer for repackaged product _____

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.41	2.4	2.4	5.08	29.26	1
Box/ Carton/ Bundle/ Inner Pack:					0.00	
Case:	7.87	10.25	7.75	8.25	655.36	12
Pallet:					0.00	

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00359746334109	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	12		40359746334107	
<input type="checkbox"/> Pallet				

COST INFORMATION

Regular Cost _____
Invoice Cost (WAC) (\$)
 As of date: _____

WHOLESALE USE ONLY:
Vendor #: _____
Whsl. Code #: _____
Fineline Code: _____



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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? (If yes, attach SDS with special instructions.) No
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)

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

Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)

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

CLASS OF TRADE RESTRICTION:

- 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)
- Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

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

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry? Website URL:

Med Guide Required No

Limited Distribution Requirement No

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

REMS:

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#:

NPI #:

Comments

Registry:

Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

