



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 6/17/2024

## PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 075317  
 Medical Device Class, if applicable:  
 DUNS: 022490515  
 Proprietary Name (If Applicable) and Established Name: Terazosin HCl Capsules  
 Selling Unit NDC: 59746-386-10 Unit of Use NDC: UPC: 3-59746-386-10-8  
 UDI: CVX Code: MVX Code:  
 Description: Terazosin Hydrochloride 10mg 1000ct Capsules  
 Active Ingredient(s): Terazosin Hydrochloride  
 URL for Additional Product Information: [www.cadista.com/products/full-product-list](http://www.cadista.com/products/full-product-list)  
 Address: 790 Township Line Road Address 2: Suite 325  
 City: Yardley State: PA Zip: 19067  
 Key Contact: Customer Service Email: [customer.service@cadista.com](mailto:customer.service@cadista.com)  
 Phone Number: (800) 313-4623 Fax: N/A  
 Product Therapeutic Classification: Benign Prostatic Hypertrophy

## 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](mailto:customer.service@cadista.com)  
 c. Special regulations for product in any states?  
 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:  
 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?  No  
 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... Orphan Drug Status   
 FDA Approval Status:   
 Allergens Present:   
 Country of Origin: US  
 Is this product covered under the Trade Agreements Act (TAA)?  Yes

## PRODUCT DESCRIPTION INFORMATION

Size: 1000 count  
 Strength: 10mg  
 Dosage Form: CAPSULE  
 Product Shape: Capsule, Size 3  
 Product Color: Light Green  
 Product Imprint: TL 386

## 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

I. Orange Book Rating:  Authorized Generic  \*If Authorized Generic, other section fields are not applicable  
 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:                    | 0.66        | 3.5                    | 3.5   | 6.4    | 78.40         | 1                 |
| Box/Carton/Bundle/Inner Pack: |             |                        |       |        | 0.00          |                   |
| Case:                         | 8.53        | 14.25                  | 10.75 | 7      | 1072.31       | 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                 |       | 00359746386108 |                     |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |                   |       |                |                     |
| <input checked="" type="checkbox"/> Case              | 12                |       | 40359746386106 |                     |
| <input type="checkbox"/> Pallet                       |                   |       |                |                     |

## COST INFORMATION

Regular Cost:   
 Invoice Cost (WAC) (\$):   
 As of date:   
 Vendor #:   
 Whsl. Code #:   
 Finline Code:

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship 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
- 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#:

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:



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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  |
|--|--|
| <p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/> Fax Number: <input style="width: 150px;" type="text"/></li> <li>c. Fax <input type="checkbox"/> Fax Number: <input style="width: 150px;" type="text"/></li> <li>d. Phone only <input type="checkbox"/> Phone No.: <input style="width: 150px;" type="text"/></li> <li>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input style="width: 150px;" type="text"/></li> </ul> <p>Minimum Order Quantity: <input style="width: 300px;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 300px;" type="text"/></p> <p>Contracted 3PL company / contact #: <input style="width: 150px;" type="text"/> Name: <input style="width: 150px;" type="text"/> Phone: <input style="width: 150px;" type="text"/></p> | <p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 200px;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" 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 style="width: 50px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 50px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text"/></p> <p>Comments: <input style="width: 400px; height: 40px;" type="text"/></p>   | <p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 200px;" 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 style="width: 150px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method: <input type="checkbox"/> Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 50px;" type="text"/></p> <p><input type="checkbox"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 50px;" type="text"/></p> <p><input type="checkbox"/> EDI: <input style="width: 50px;" type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction:  |  |
| <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: 400px; height: 40px;" type="text"/></p>   |  |
| Other Data Information Required to Process PO:   | Return Instructions  |
| <p>Patient Procedure Date: <input style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 250px;" type="text"/></p> <p>Physician State License #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 250px;" type="text"/></p>   | <p>Contact # if product is received damaged: <input style="width: 100px;" type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input style="width: 250px;" 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: 400px; height: 40px;" type="text"/></p>   |
| Miscellaneous Notes:   | ADDITIONAL INFORMATION   |
| <input style="width: 450px; height: 100px;" type="text"/>  | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |