Release 08-09-13

☑ Final Version

# Standard Pharmaceutical Product Information

☐ New Item ☐ Promotion/Deal ☐ Open Stock ☑ Post Launch Change

Date: 2/11/2014

copyright Aug 2013

## PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| Company Name: | Jubilant Cadista Pharmaceuticals Inc. | ☐ NDA ☑ ANDA ☐ BLA ☐ Med Devic | |
| Application number for NDA/ ANDA/ BLA, Med Device: | A090901 | | |
| Rx Product / Proprietary Name: | Pantoprazole DR Tablets | | |
| NDC: | 59746-0283-90 | UPC: | 3-59746-283-90-2 |
| CVX Code: | | MVX Code: | |
| Description: | Pantoprazole 20mg Delayed Release Tablets 90ct. | | |
| Active ingredients: | Pantoprazole | | |
| URL for additional product information: | www.cadista.com | | |
| Address: | 207 Kiley Drive | Address 2: | |
| City: | Salisbury | State: MD | Zip: 21801 |
| Key Contact: | Jackie Emershaw | Email: | Jackie.Emershaw@cadista.com |
| Phone Number: | (410) 912-3722 | Fax: | (215) 443-9646 |

## FOR GENERIC DRUG PRODUCTS

| | | | |
|---|---|---|---|
| I. Orange Book Rating: | AB | II. Brand Name: | Protonix ® |
| III. Generic Equivalent for Brand: | Pantoprazole | | |

## ADDITIONAL PRODUCT INFORMATION

| | Level | How? | | GTIN-14 |
|---|---|---|---|---|
| Serialized? ○ Yes ◉ No | ☐ Item | ☐ 2D | ☐ Linear | ☐ RFID |
| | ☐ Case | ☐ 2D | ☐ Linear | ☐ RFID |
| | ☐ Pallet | ☐ 2D | ☐ Linear | ☐ RFID |

Is the Product... ☑ Direct Ship Item ☐ Direct and Drop Ship ☐ Drop Ship only item (See new page 3.)

a Legend Device? ◉ Yes ○ No
a State Control? ○ Yes ◉ No
ARCOS reportable? ○ Yes ◉ No
Co-Licensed? ○ Yes ◉ No
Repackaged? ○ Yes ◉ No
Controlled Substance? ○ Yes ◉ No
Schedule No.? (incl. N for non-narcotic)

Hazardous Material / Cytotoxic Agent? ○ *Ye ◉ No

Is Item... ○ Unit Dose ○ Unit of Use

If Unit Dose, is item bar coded to unit dose for hospital scanning? ○ Yes ○ No

Is it reverse numbered? ○ Yes ◉ No

## SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

- ☐ I. Freezer – between -25 and -10 C (-13° – 14° F)
- ☐ II. Cold – between 2 and 8 C (36° – 46° F)
- ☐ III. Cool – between 8 and 15 C (46° – 59° F)
- ☐ IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
- ☐ V. Avoid Excessive Heat – above 40 C (>104° F)
- ☐ VI. Other Temperature Range Requirement (write in)
- ☑ VII. No Requirement

b. Contact for temperature excursion questions:
Name: Customer Support Number: (800) 313-4623

Is this product to be shipped to customers on ice? ○ Yes ◉ No
Is this product to be shipped to customers on dry ice? ○ Yes ◉ No

c. Special regulations for this product in certain states? ○ *Ye ◉ No
Special returns requirements for this product? ○ *Ye ◉ No

d. Store product (unit of sale) upright? ○ Yes ◉ No
Protect product (unit of sale) from light? ○ Yes ◉ No

e. Shelf life: 24 Months
Initial shelf life at launch (if different): 24 Months

## ITEM AND PACKING INFORMATION

### Order Information

| Unit of Sale | What is the NDC selling unit? |
|---|---|
| ☑ Bottle | 1 Case of 48 Bottles |
| ☐ Box / Carton | |
| ☐ Ampule | (Write-in, e.g. 1 Box of 10 Vials) |
| ☐ Glass | |
| ☐ Tube | Minimum order quantity? ◉ Yes ○ No |
| ☐ Vial Liquid Sgl | If Yes, how many of which package type? |
| ☐ Vial Liquid Multil | |
| ☐ Vial Powder Sgl | 48 ☑ Eact |
| ☐ Vial Powder Multi | ☐ Inner / Carton |
| ☐ Other: Write In | ☐ Case |

| | Weight Lbs. | Dimensions (US msmts.) Depth | Height | Width: | Volume (Cube) | # Pieces: |
|---|---|---|---|---|---|---|
| Item: | 0.0661 | 1.88 | 3.95 | 1.88 | 13.96088 | 1 |
| Box/ Carton: | | | | | 0 | |
| Case: | 5.07 | 15.5 | 5.6 | 11.81 | 1025.108 | 48 |
| Pallet: | | | | | 0 | |

UPC: Case: Carton:

### PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy: ☐ Each ☐ Gram ☐ Millilite

### Other Product Information

| | |
|---|---|
| Size/Strength/Form: | 90/20mg/TAB |
| Product Shape: | Round |
| Product Color: | Light Pink |
| Product Imprint: | C283 |

### COST INFORMATION

| Regular Cost Per Unit of Sale ($) | Invoice Cost (WAC) ($) | Federal Excise Tax Per Unit of Sale |
|---|---|---|
| | $12.50 | |

### WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

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

*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:

# Standard Pharmaceutical Product Information (Page 2)

CHDMA

*For Designated Drop Ship Only Products, Please Use Page 3*

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? ○ Yes ◉ No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? ○ Yes ◉ No

- ☐ Carcinogen
- ☐ Reproductive Toxicant
- ☐ Both
- ☐ Warning appears on label

**Hazardous Waste Identification**

EPA Hazardous Waste Code:

c. Contact Hazard? ○ Yes ◉ No

d. Does this product require special clean-up instructions? ○ Yes ◉ No (If yes, attach MSDS with special instructions.)

e. Does the product contain DEHP? ○ Yes ◉ No

Is this product regulated for shipment by the DOT? ○ Yes ◉ No (if yes, answer a-d below and provide MSDS)

Is this a reportable quantity? ○ Yes ◉ No

RQ Threshold:

Is this a marine pollutant? ○ Yes ◉ No

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard? ○ Yes ○ No

Is this product shipped utilizing an authorized DOT exception or Special Permit? ○ Yes ◉ 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#

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

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

## REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? ○ Yes ◉ No

If Yes, is it managed with a pharmacy registry? ○ Yes ○ No

Website URL:

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

## ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

- ☐ Organic
- ☐ Antineoplastic
- ☐ Corrosive
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Oxidizer
- ☐ Aerosol Class; Identify NFPA Storage Level: ○ Level 1 ○ Level 2 ○ Level 3
- ☐ Listed Chemical (List I or II) (Indicate or Write-in below):
  - ☐ Ephedrine
  - ☐ Pseudoephedrine
  - ☐ Phenylpropanolamine
  - ☐ Iodine (≥2.2%)
  - ☐ Other:

## RETURN INSTRUCTIONS

Contact # if product recvd damaged: (410) 912-3722

Is product returnable for credit: ◉ Yes ○ No

URL/Link to returns policy: www.cadista.com

Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? ○ Yes ◉ No

Comments:

## CLASS OF TRADE RESTRICTION:

No restriction: Sold to both retail pharmacy, hospitals, clinics and physician offices ◉ Yes ○ No

Restricted to retail pharmacy only: ○ Yes ◉ No

Restricted to hospital, clinics, and physician offices only: ○ Yes ◉ No

Restricted from US territories? (explain in comments) ○ Yes ◉ No

Comments:

## ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

## MISCELLANEOUS NOTES and/or Image of Product Barcode: