Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Post Launch Change | [x] Final Version | **Date:**

PRODUCT INFORMATION

Company Name: Jubilant Cadista Pharmaceuticals Inc. | **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 202956
DUNS: 022490515
Proprietary Name (If Applicable) and Established Name: Zolmitriptan ODT Tablets
Selling Unit NDC: 59746-0462-13 | **Individual Unit NDC:** | **UPC:** 359746462130
UDI: | **CVX Code:** | **MVX Code:**
Description: Zolmitriptan ODT Tablets 5mg 3ct
Active Ingredient(s): Zolmitriptan
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
Product Therapeutic Classification:

ADDITIONAL PRODUCT INFORMATION

Is the Product…
a legend device? Yes
reverse numbered? No
co-licensed? No
Is the Product… Direct-Ship Only
Is the Product…

If Unit Dose, is item bar coded to unit dose for hospital scanning?
If Unit Dose NDC, indicate NDC here:
Country of Origin
Is this product covered under the Trade Agreements Act (TAA)?

PRODUCT DESCRIPTION INFORMATION

Size: 3ct
Strength: 5mg
Dosage Form: TAB
Product Shape: Round
Product Color: White
Product Imprint: c | k

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB
II. Generic Equivalent to What Brand?: Zomig-ZMT®

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes | **GLN:** 8902805000006
Is product exempt from DSCSA? No
If yes, select exemption:
Other exemption - Write in:
Is product repackaged? No | **If Yes, was original product purchased direct from mfr?**
Is product sold by manufacturer's exclusive distributor? No
Has FDA granted waiver/exception/exemption for product? No | **If yes, attach documentation from FDA.**

GTIN PRODUCT INFORMATION

Serialized? Yes
If not, when?
Items aggregated?

	Level	Saleable Unit				Quantity	GTIN-14
x	Item		x	2D	Linear	1	00359746462130
	Box/Carton/Bundle/Inner Pack			2D	Linear		
x	Case	x	x	2D	Linear	120	40359746462138
	Pallet			2D	Linear		
				2D	Linear		
				2D	Linear		
				2D	Linear		
				2D	Linear		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range: Controlled Room – between 20 and 25 C (68° – 77°
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. Contact for temperature excursion questions:
Name: Customer Support
Number: (800) 313-4623
Group E-mail:

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): 24 Months

ORDER INFORMATION

Unit of Sale

	Bottle
x	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sql
	Vial Power Multi
	Other: Write In

What is the NDC selling unit?
1 Case of 120 cartons
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

120	Each
	Inner/Carton/Pack
	Case

PHARMACY ORDER / BILL UNIT

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

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.06613868	3.07087	1.9685	1.87	42.75	1
Box/Carton/Bundle/ Inner Pack:					0	
Case:	7.82641	13.3858	5.31496	12.5984	896.313062	**120**
Pallet:					0	
UPC:	**Case:**					
	Carton:					

COST INFORMATION

Regular Cost
Invoice Cost (WAC) ($) $11.07
Federal Excise Tax Per Unit of Sale
As of date:

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

Attach copy of SAFETY DATA SHEET (SDS) 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)

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?	No
(If yes, attach SDS with special instructions.)	
e. Does the product contain DEHP?	No
Is this product regulated for shipment by DOT or IATA?	No
(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?	

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#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard
- ☐ Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?

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

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	No
Controlled by State(s)?	
ARCOS Reportable?	
Schedule No. (inc. N for non-narcotic)	
Controlled Substance Code	
Listed Chemical (List I or II)	
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:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: (410) 912-3722

Is product returnable for credit:

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? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI	Yes		
b. Autofax	Yes	Fax Number:	
c. Fax	Yes	Fax Number:	
d. Phone only		Phone No.:	
e. Supplier Web Site only		Site Address:	

Minimum Order Quantity: 120

Supplier's Customer Service Number: (410) 912-3722

Contracted 3PL company / contact #: Name:

Phone:

Standard Order Receipt and Processing

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:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

Days of week overnight is available:

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method: Phone: Phone #:

Fax: Fax #:

EDI:

Overnight Fees apply:

Other fees apply:

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:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Return Instructions

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?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?