



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final VersionDate: 

PRODUCT INFORMATION	
Company Name:	Sciegen Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	211829
DUNS:	079391286
Proprietary Name (If Applicable) and Established Name:	Ranolazine Extended Release Tablets, 500mg, 60s per Bottle
Selling Unit NDC:	50228-423-60
Individual Unit NDC:	1 Bottle
UPC:	350228423601
UDI	
CVX Code:	
MVX Code:	
Description:	peach, oblong shaped, film-coated, extended release tablet debossed with "423" on one side and "SG" on the other side
Active Ingredient(s):	Ranolazine
URL for Additional Product Information:	
Address:	89 arkay drive
City:	Hauppauge
Key Contact:	Siva Reddy.P.V
Phone Number:	631-434-2723, 631-524-5509
Product Therapeutic Classification:	Treatment of chronic angina
Application:	ANDA
State:	NY
Zip:	11788
Email:	sivareddy@sciegenpharm.com
Fax:	631-357-3178

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77° F)
Temperature Range	
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:	Siva Reddy.P.V
Number:	631-524-5509
Group E-mail:	sivareddy@sciegenpharm.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

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

PRODUCT DESCRIPTION INFORMATION	
Size:	0.6496" X 0.3150"
Strength:	500 mg
Dosage Form:	Extended-release Tablets
Product Shape:	Oblong Shape
Product Color:	peach
Product Imprint:	"423" on one side and SG on the other side

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> yes Bottle	1 Bottle
<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 Power Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	24 Bottles Each
	Per Case Inner/ Carton/Pack
	3 Case Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Ranexa
<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:
bottle	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> 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?	
Has FDA granted waiver/exception/exemption for product?	No
GLN:	350228000000
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.06	NA	3	1.7	#VALUE!	60 tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	NA	NA
Case:	1.5	11.5	4.1	7.2	339.48	24 bottles per Case
Pallet:	264	48	54	40	103680	220 Cases per Pallet
UPC:	Case:	350228423601				
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
Yes	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00350228423601		
If not, when?	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>				
Items aggregated?	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	24	20350228423605		
	<input type="checkbox"/> Pallet	<input type="checkbox"/>				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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.)
- e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT or 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?  
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

<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<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:**   
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:   
Wholesale distributor support:   
Provider Name:   
Site Enrollment Number assigned by Supplier:   
DEA #:   
PCPDP #:   
NPI #:

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No
- Controlled by State(s)?  No
- 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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

Comments

**Registry:**   
Registry Program Contact Name:  Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1877-671-6307

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  No  
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
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> _____ b. Autofax <input type="checkbox"/> _____ Fax Number: _____ c. Fax <input type="checkbox"/> _____ Fax Number: _____ d. Phone only <input type="checkbox"/> _____ Phone No.: _____ e. Supplier Web Site only <input type="checkbox"/> _____ Site Address: _____ Minimum Order Quantity: _____ Supplier's Customer Service Number: _____ Contracted 3PL company / contact #: Name: _____ Phone: _____	<b>Purchase order daily receipt cut off time by supplier</b> 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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: _____ Drop Ship service fee billed with each order: _____ Drop Ship miscellaneous fees billed: _____ Comments: _____	<b>Overnight receipt available:</b> _____ PO Receipt cut off time: _____ Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday  <b>Priority Overnight receipt available:</b> _____ PO Receipt Cut off time: _____  <b>Saturday Overnight receipt available:</b> _____ PO Receipt Cut off time: _____ Order receipt method: Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ Overnight Fees apply: _____ Other fees apply: _____
Class of Trade Restriction:	Return Instructions
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> _____ Restricted to retail pharmacy only: _____ Restricted to hospital, clinics, and physician offices only: _____ Restricted from US territories? (explain in comments) _____ Comments: _____	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? _____
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____	Is product order for scheduled patient procedure? _____ Is product order for restocking purposes? _____
Miscellaneous Notes:	
_____	