



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

Version 2021 Introduction Type: [ ] Final Version Date: [ ]

## PRODUCT INFORMATION

**Company Name:** Sciegen Pharmaceuticals Inc **Application:** ANDA  
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 206381  
**Medical Device Class, if applicable:** [ ]  
**DUNS:** 079391286  
**Proprietary Name (if Applicable) and Established Name:** Rosuvastatin Tablets, USP 10 mg, 90's count per bottle  
**Selling Unit NDC:** 50228-117-90 **Unit of Use NDC:** 1 bottle **UPC:** 350228117906  
**UDI:** [ ] **CVX Code:** [ ] **MX Code:** [ ]  
**Description:** Pink colored, round, biconvex, film coated tablets, debossed with SG on one side and 117 on other side.  
**Active Ingredient(s):** Rosuvastatin  
**URL for Additional Product Information:** [ ]  
**Address:** 89 arkay drive **Address 2:** [ ]  
**City:** Hauppauge **State:** NY **Zip:** 11788  
**Key Contact:** Siva Reddy,P.V **Email:** sivareddy@sciegenpharm.com  
**Phone Number:** 631-424-2723, 631-524-5509 **Fax:** 631-357-3178  
**Product Therapeutic Classification:** Hyperlipidemia

## 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° F)  
 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:** Siva Reddy, P.V.  
**Number:** 631-424-2727 XT 107, 631-524-5509  
**Group E-mail:** sivareddy@sciegenpharm.com  
**c. Special regulations for product in any states?** [ No ]  
 Special returns requirements for this product? [ No ]  
**d. Store product (unit of sale) upright?** [ Yes ]  
 Protect product (unit of sale) from light? [ ]  
**e. Shelf life:**  
 Initial shelf life at launch (if different): [ 24 ] Months  
 [ 24 ] Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device? [ No ]  
 if yes, enter class # [ ]  
 if yes, list NDCs of component parts reverse numbered? [ ]  
 co-licensed? [ No ]  
 latex-free? [ ]  
 preservative-free? [ ]  
 correctional institution block? [ ]  
 opioid? [ ]  
 Cannabinoid? [ ]  
 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... Unit of Use** [ ]  
**Orphan Drug Status** [ ]  
**FDA Approval Status** [ ]  
**Allergens Present** [ ]  
**Country of Origin** USA [ ]  
 Is this product covered under the Trade Agreements Act (TAA)? [ Yes ]

## PRODUCT DESCRIPTION INFORMATION

**Size:** 0.2283  
**Strength:** 10 mg  
**Dosage Form:** Tablet  
**Product Shape:** Round  
**Product Color:** Pink  
**Product Imprint:** "SG" on one side and "117" on other side

## ORDER INFORMATION

**Unit of Sale**  
 Yes 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?**  
 1 Bottle of 90 Tablets  
 (Write-in, e.g. 1 Box of 10 Vials)  
**Minimum order quantity?** [ Yes ]  
**If Yes, how many of which package type?**  
 24 Bottles Each  
 per Case Inner/ Carton/Pack  
 1 Cases Case

## FOR GENERIC DRUG PRODUCTS

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

## PHARMACY ORDER / BILL UNIT

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

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

**Does supplier meet DSCSA definition of manufacturer?** [ Yes ]  
**Is product exempt from DSCSA?** [ No ]  
**GLN:** 0350228000000  
**GCP:** [ ]  
**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:	0.05	NA	1.6	2.9	#VALUE!	90 tablets per bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	1.8	9.4	6.3	3.5	207.27	24 bottles per case
Pallet:	400	48	40	54	103680	200 case per pallet

## 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	[ ]	00350228117906	[ ]
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	[ ]	[ ]	[ ]	[ ]
<input checked="" type="checkbox"/> Case	24	[ ]	20350228117900	[ ]
<input type="checkbox"/> Pallet	[ ]	[ ]	[ ]	[ ]

## COST INFORMATION

**Regular Cost** [ ]  
**Invoice Cost (WAC) (\$)** \$5.46  
**As of date:** [ ]  
**WHOLESALE USE ONLY:**  
**Vendor #:** [ ]  
**Whsl. Code #:** [ ]  
**Fineline Code:** [ ]



Version 2021

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?

RQ Threshold:

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- (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      Controlled Substance Code
- Controlled by State(s)?       Listed Chemical (List I or II)
- ARCOS Reportable?       If yes, indicate which:
- Schedule No.       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:

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

Release DATE

### SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No

If yes, indicate which:

### 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

Limited Distribution Requirement

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:  6315245509

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?

