



# 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 20 mg, 500's count per bottle

**Selling Unit NDC:** 50228-118-05 **Unit of Use NDC:** 1 bottle **UPC:** 350228118057

**UDI:**  **CVX Code:**  **MX Code:**

**Description:** Pink colored, round, biconvex, film coated tablets, debossed with SG on one side and 118 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

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?  No

If yes, enter class #

If yes, list NDCs of component parts

reverse numbered?  No

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... 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:** 0.2913

**Strength:** 20 mg

**Dosage Form:** Tablet

**Product Shape:** Round

**Product Color:** Pink

**Product Imprint:** "SG" on one side and "118" on other side

## ORDER INFORMATION

**Unit of Sale**

|                                     |                   |        |
|-------------------------------------|-------------------|--------|
| <input checked="" type="checkbox"/> | Yes               | Bottle |
| <input type="checkbox"/>            | Box/Carton        |        |
| <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   |        |

**What is the NDC selling unit?**  1 Bottle of 500 Tablets

(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes

**If Yes, how many of which package type?**

|                          |            |                   |
|--------------------------|------------|-------------------|
| <input type="checkbox"/> | 24 Bottles | Each              |
| <input type="checkbox"/> | per Case   | Inner/Carton/Pack |
| <input type="checkbox"/> | 1 Cases    | Case              |

## 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?:** Crestor

## 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

**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:** 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:                    | 0.24        | NA                     | 2.1   | 3.9    | #VALUE!       | 500 tablets per bottle |
| Box/Carton/Bundle/Inner Pack: | NA          | NA                     | NA    | NA     | #VALUE!       | NA                     |
| Case:                         | 6.39        | 12.6                   | 8.4   | 4.5    | 476.28        | 24 bottles per case    |
| Pallet:                       | 704         | 48                     | 40    | 54     | 103680        | 104 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                 |       | 00350228118057 |                     |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |                   |       |                |                     |
| <input checked="" type="checkbox"/> Case              | 24                |       | 20350228118051 |                     |
| <input type="checkbox"/> Pallet                       |                   |       |                |                     |

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) (\$)**  \$33.57

**As of date:**

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**



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

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: UN2811
- b. Proper Shipping Name: \_\_\_\_\_
- c. DOT Hazard Class: Toxic SOLID , Organic N.O.S (Lacosamide)
- d. Packing Group: III
- e. Inhalation Hazard?

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?

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? \_\_\_\_\_

