



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 40 mg, 500's count per bottle

Selling Unit NDC: 50228-119-05 **Unit of Use NDC:** 1 bottle **UPC:** 350228119054

UDI: [] **CVX Code:** [] **MVX Code:** []

Description: Pink colored, oval shaped, biconvex, film coated tablets, debossed with SG on one side and 119 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?

Special returns requirements for this product? No

d. Store product (unit of sale) upright? Yes

e. Shelf life: Protect product (unit of sale) from light? Yes

Initial shelf life at launch (if different): 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: 0.2756 x 0.4764

Strength: 40 mg

Dosage Form: Tablet

Product Shape: Oval

Product Color: Pink

Product Imprint: "SG" on one side and "119" 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 checked="" type="checkbox"/>	12 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: 035022800000

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:	0.44	NA	2.6	5.12	#VALUE!	500 tab per bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	5.73	10.5	7.9	5.75	476.9625	12 bottles per case
Pallet:	636	48	40	54	103680	110 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	[]	00350228119054	[]
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	[]	[]	[]	[]
<input checked="" type="checkbox"/> Case	12	[]	20350228119058	[]
<input type="checkbox"/> Pallet	[]	[]	[]	[]

COST INFORMATION

Regular Cost []

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

As of date: []

WHOLESALE USE ONLY:

Vendor #: []

Whsl. Code #: []

Fineline Code: []



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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?

