



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 5 mg, 90's count per bottle
 Selling Unit NDC: 50228-116-90 Unit of Use NDC: [] 1 bottle UPC: 350228116909
 UDI: [] CVX Code: [] MVX Code: []
 Description: Pink colored, oval shaped, biconvex, film coated tablets, debossed with SG on one side and 116 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
 Protect product (unit of sale) from light? [] Yes

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 # []
 a product kit? []
 if yes, list NDCs of component parts reverse numbered? []
 co-licensed? [] No
 latex-free? [] No
 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: 0.1740 x 0.3000
 Strength: 5 mg
 Dosage Form: Tablet
 Product Shape: Oval
 Product Color: Pink
 Product Imprint: "SG" on one side and "116" 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
 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:	0.05	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
X Item/Each	1		00350228116909	
X Case	24		20350228116903	
Box/Carton/Bundle/Inner Pack				
Pallet				

COST INFORMATION

Regular Cost []
 Invoice Cost (WAC) (\$) \$5.46
 As of date: []

WHOLESALE USE ONLY:
 Vendor #: []
 Whsl. Code #: []
 Fineline Code: []



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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?

