



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): | 205236 |
| DUNS: | 079391286 |
| Proprietary Name (if Applicable) and Established Name: | Hydralazine Hydrochloride Tablets, USP 25 mg, 100's per Bottle |
| Selling Unit NDC: | 50228-183-01 |
| Individual Unit NDC: | 1 Bottle |
| UPC: | 350228183017 |
| UDI | |
| CVX Code: | |
| MVX Code: | |
| Description: | Orange, round tablets debossed with "SG" on one side and "183" on the other side. |
| Active Ingredient(s): | Hydralazine Hydrochloride |
| 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: | Anti Hypertensive |
| Address 2: | |
| 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. | |
| Temperature Range | Controlled Room – between 20 and 25 C (68° – 77° F) |
| 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? | |
| Special returns requirements for this product? | No |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | No |
| e. Shelf life: | |
| Initial shelf life at launch (if different): | 24 Months |

| 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: | 0.2756 |
| Strength: | 25mg |
| Dosage Form: | Tablets |
| Product Shape: | Round |
| Product Color: | Orange |
| Product Imprint: | "SG" on one side and "183" on the other side |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> yes | 1 Bottle of 100 tablets |
| <input type="checkbox"/> Bottle | (Write-in, e.g. 1 Box of 10 Vials) |
| <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 | |
| | Minimum order quantity? Yes |
| | If Yes, how many of which package type? |
| | 24 Bottles Each |
| | per Case Inner/Carton/Pack |
| | 3 Cases Case |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | AA |
| II. Generic Equivalent to What Brand?: | Apresoline |
| <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 | X Each |
| (Write-in, e.g. 1 Vial) | 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? | |
| 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. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width | | |
| Item: | 0.07 | NA | 3.45 | 2.1 | #VALUE! | 100 Tablets per Bottle |
| Box/Carton/Bundle/Inner Pack: | NA | NA | NA | NA | #VALUE! | NA |
| Case: | 2.5 | 13.9 | 5 | 9.2 | 639.4 | 24 Bottles per Case |
| Pallet: | 330 | 48 | 48 | 40 | 92160 | 117 Cases per Pallet |
| UPC: | Case: | 350228183017 | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | | | | |
|--------------------------|--------|---------------|------|----------|----------------|--|
| Serialized? | Level | Saleable Unit | | Quantity | GTIN-14 | |
| | | Item | Unit | | | |
| Yes | | X | X | 1 | 00350228183017 | |
| If not, when? | | X | X | 24 | 20350228183011 | |
| Items aggregated? | No | | | | | |
| | Case | | | | | |
| | Pallet | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| 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? No
 (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# _____

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: _____

SDS Hazard Classification

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen 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 #: _____

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 |
|--|--|
| <p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| <p>Expedited freight fees billed with each order: <input type="checkbox"/></p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/></p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p> | <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction: | Return Instructions |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p> | <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 50px;" type="text"/></p> |
| Other Data Information Required to Process PO: | ADDITIONAL INFORMATION |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> |
| Miscellaneous Notes: | |
| <input style="width: 100%; height: 100px;" type="text"/> | |