



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): 215069
 Medical Device Class, if applicable: []
 DUNS: 079391286
 Proprietary Name (If Applicable) and Established Name: Levetiracetam Tablets, USP 250 mg, 500's count per bottle
 Selling Unit NDC: 50228-470-05 Unit of Use NDC: [] 1 bottle UPC: 350228470056
 UDI [] CVX Code: [] MVX Code: []
 Description: White oblong shape film coated scored tablet debossed with "SG470" on scored side and plain on other side
 Active Ingredient(s): Levetiracetam
 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: Treatment of Partial onset seizures

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? []

e. Shelf life:
 Initial shelf life at launch (if different): [] 18 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: []

PRODUCT DESCRIPTION INFORMATION

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

Size: 500
 Strength: 250 mg
 Dosage Form: Tablet
 Product Shape: Oblong
 Product Color: White
 Product Imprint: "SG470" on scored side and plain 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 500 Tablets (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity? [] Yes

If Yes, how many of which package type?
 12 Bottles Each
 per Case Inner/ Carton/Pack
 1 Cases Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AP
 II. Generic Equivalent to What Brand?: Keppra
 [] 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:	0.38	NA	2.614	4.99	#VALUE!	500 tablets per bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	4.56	12.1	8.4	4.5	457.38	12 bottles per case
Pallet:	730	48	40	48	92160	160 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		00350228470056	
Box/Carton/Bundle/Inner Pack				
X Case	12		20350228470050	
Pallet				

COST INFORMATION

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

WHOLESALE USE ONLY:
 Vendor #: []
 Whsl. Code #: []
 Finline 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?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 - Is the product a CA Prop 65 carcinogen?
 - Is the product a CA Prop 65 reproductive toxicant?
 - Does the product label bear a CA Prop 65 warning?

- c. Contact Hazard?
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

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?

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?

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? 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? If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

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:

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?



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

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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"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></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="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input 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:	
<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 type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<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>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 type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><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>