

Standard Pharmaceutical Product Information (Rx Product Only)

					Intro	oduction Type:		New Item	0	Final Version			Date:		
			PRODUCT INFORMAT	ION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	S*	
Company Name: Application Number for NE	Sciegen Pharmaceut			204989		Application	n:	ANDA	a. Temperature – Indio	cate the USP temper	rature range			een 20 and 2	5 C (68° – 77° I
DUNS:	079391286	.,,							Other Te	emperature Range Re	equirement				
Proprietary Name (If Applica		Name: Gabapenti	n capsules, USP 100 mg ,5							rite in)					I
Selling Unit NDC: UDI	50228-179-05		Individual Unit NDC: CVX Code:	1 Bottle	MVX	UPC: 35022 X Code:	28179058		ls this p	oduct to be shipped	to customers	on ice?		No	
Description:	White to Off white po on body with black in		gelatin capsules with opaque	e White colored cap and	d opaque Whi	ite colored body im	nprinted "SG	6" on cap and "179"	: 1	roduct to be shipped				No	- -
Active Ingredient(s):	on body with black in	Gabapentin							b. Contact for tempera	ature excursion que	stions:	Siva Reddy.	P V		
URL for Additional Product									Number	:		631-524-550)9		
Address:	89 arkay drive			State	Address		4470	00	Group E	-mail:		sivareddyp@	sciegenpha	rm.com	
City: Key Contact:	Hauppauge Siva Reddy.P.V			State:		Zip: dyp@sciegenphar	1178 rm.com	88	c. Special regulations	for product in any s	states?			No	
Phone Number:	631-434-2723, 631-5	24-5509		Fax:	631-357					returns requirements		ict?		140	
Product Therapeutic Classif	fication:	Anticonvulsant													_
ADDITION	AL PRODUCT INFORM	IATION			PRODUCT	DESCRIPTION II	NEODMATIC	ON	d. Store product (unit	, , -	a) fram limbt?			Yes	_
	AL PRODUCT INFORM	IATION			PRODUCT	DESCRIPTION II	NFORMATIC	ON	11	product (unit of sale	e) from light?			No No	_] Mantha
Is the Product a legend device?		No							e. Shelf life:	nelf life at launch (if	different):			24	Months Months
reverse numbered?		No		Size:		16mm-Size 3				·					
co-licensed?		No Direct-Ship Only		Strength:		100 mg				C	ORDER INFO	RMATION			
Is the Product		Unit of Use							Unit of S	Sale		What is the	NDC selling	unit?	
				Dosage Fo	orm:	Capsule			yes	Bottle		1 Bottle of 5	00 Capsules		
If Unit Dose, is item bar code	ed to unit dose for hosp	oital scanning?								Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
If Unit Dose NDC, indicate N	NDC here:			Product SI	hape:	Capsule				Ampule Glass		Minimum o	rder quantit	y?	Yes
Country of Origin		USA		Product Co	olor:	white color cap/w	hite color bo	ody		Tube					
Country of Origin						00 0 14	170 5 1			Vial Liquid Sgl Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
Is this product covered unde	er the Trade Agreement	s Act (TAA)?		Product In	nprint:	SG on Cap and 1	179 on Body			Vial Powder Sql		12 Bottles	Each		71
									l	Vial Power Multi Other: Write In		per case	Inner/Cartor	n/Pack	
			FOR GENERIC DRUG PRO	DUCTS						Other, write in		3 Cases	Case		
					uthorized Ger	neric *If Aut	thorized Gen	neric, other section		PHAR	RMACY ORDE	FR / BILL UN	Т		
I. Orange Book Rating:	AB				dunonzea Ger		are not appli	•	Rec. sell unit to custo			Rx billing u		acv.	
II. Generic Equivalent to Wh		Neurontin (gabapentin) o	apsules						bott			X	Each	iuoy.	
		DDIIO CUDDI V	CHAIN SECURITY ACT /	ACCCA) INFORMATION					(Write-in, e.g. 1 Vial)		-		Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFORMATION	N								Milliliter		
Does supplier meet DSCSA Is product exempt from DSC		turer?	Yes	GLN:	3502280	000000				ITEM A	ND PACKING	INFORMAT	ON		
If yes, select exemption:	23A ?	1	<u> </u>								Dime	nsions (US m	ısmts.)	Volume	" D'
Other exemption - Write in	:									Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged? Is product sold by manufact	turer's exclusive distr	ibutor?	0	If Yes, was ori from mfr?	ginal produc	ct purchased direc	ct		Item:	0.3	NA	5.25	2.95	#VALUE!	500 Casules per Bottle
Has FDA granted waiver/exc	ception/exemption for	product?	No	If yes, attach o	documentatio	on from FDA.			Box/Carton/Bundle/ Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
			GTIN PRODUCT INFORM	ATION aleable					Case:	4	12	7.4	9.2	816.96	12 Bottles per Case
			Level	Unit		Quant			Pallet:	400	48	48	40	92160	90 cases
Serialized?	Yes		tem	X X 2D		Linear 1	0035	50228179058	LIDO.				40	32100	per Pallet
If not, when? Items aggregated?	No		Box/Carton/Bundle/Inner Pack Case	X 2D 2D	<u> </u>	Linear 12	2035	50228179052	UPC:	Case: Carton:	350228179	058			
nome aggregates.			Pallet	2D		Linear				•					
				2D		Linear			COST	INFORMATION			WHOLESAL	ER USE ON	LY:
				2D 2D	-	Linear Linear			Regular Cost			Vendor #:			
				2D		Linear			Invoice Cost (WAC) (\$			Whsl. Code			
				· 					Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:		
									As of date:			1			
		Att	ach copy of SAFETY DATA	SHEET (SDS) or non h	nazard letter, f	PACKAGE INSER	RT, LABEL A	AND PHOTO OF PRO	DUCT PACKAGING and E	BARCODE.		•			
*Please provide any addition	nal information on page		·			w p. 3 for Designa			Signatu						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	IAZARD 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? No 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? 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	SDS Hazard Classification X
c. DOT Hazard Class	EPA Hazardous Waste Code:
d. Packing Group	El Milazardodo Wasio Osas.
e. Inhalation Hazard?	
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? No Is this a reportable quantity?	Comments / Details: (For example, iPledge program?)
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#	REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: PCPDP #:
	NPI #:
ADD'L STORAGE INFORMATION Is the Product Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. (inc. N for non-narcotic) Controlled Substance Code	Registry: Registry Program Contact Name: Comments Phone:
Listed Chemical (List I or II)	RETURN INSTRUCTIONS
If yes, indicate which:	
Is it a scheduled listed chemical product?:	Contact tel. # if product received damaged: 6315245509
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy:
Restricted to retail pharmacy only:	Special regulations or returns requirements for this product in certain states? No
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?
Comments:	
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax Fax Number:	
c. Fax Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only e. Supplier Web Site only Phone No.: Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:	Ships for second day receipt:
Supplier's Customer Service Number:	Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:	
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:	Days of week overnight is available:
Comments:	Tuesday
	Wednesday
	Thursday
	Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time:
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:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone #:
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)	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: Phone #: Fax #:
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:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Fax: Fax: EDI:
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)	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply:
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:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: Fax: EDI: Overnight Fees apply: Other fees apply:
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: Other Data Information Required to Process PO:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply: Return Instructions
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: Other Data Information Required to Process PO: Patient Procedure Date:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: Fax: EDI: Overnight Fees apply: Other fees apply: Return Instructions Contact # if product is received damaged:
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: Other Data Information Required to Process PO: Patient Procedure Date: Physician Name:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply: Return Instructions Contact # if product is received damaged: Is product returnable for credit:
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