

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

Version 2021						Introduction Type:	New Item] [x Final Version			Date:	08-14	4-2024
			PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: CREEKWOOD PHARMACEUTICALS LLC Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN				2	04989				emperature Range	Controlled Room			68° – 77° F)	
Medical Device Class, if applica	ble:									1				
DUNS:	118582565							C	ther Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Name:	Gabap	entin capsules, USP 300 m	ig ,100's per Bo					(write in)					
Selling Unit NDC:	82619-143-01		Unit of Use NDC:		82619-143-01		2619143010	N	lotes					
UDI	NA		CVX Code:			MVX Code: NA								
Description: White to off white powder filled in size "1" hard gelatin capsules with opaque Yellow colored cap and opaque Yellow colored body imprinted "SG" on Is this product to be shipped to customers on ice? No												_		
cap and "180" on body with black ink Is this product to be shipped to customers on dry ice? No Active Ingredient(s): Gabapentin														
Active ingrediency. Galagement														
URL for Additional Product Inform	nation:								lame:		SUJIT SAK	PAL		
Address:	1130 US 46 W					Address 2: Suite	9 21	N	lumber:		551-303-93			
City:	Parsippany				State:		07054	Group E-mail: sujit@creekwoodphar				arma.com		
Key Contact:	Paul Thomas				Email:	paul@creekwoodpl	harma.com	c. Special regulations for product in any states?					NI-	-
Phone Number:	1-732-344-022	ulcont			Fax:			-			2		No	-
Product Therapeutic Classification: Anticonvulsant Special returns requirements for this pro											(No	
	ADDITIONAL PR					PRODUCT DESC	RIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				Yes	1
The product is?			Is the Product	Direct-Ship	Only				rotect product (unit of s	ale) from light?			No	1
a legend device?	No		Is the Product	Unit of Use	Unity		19mm -Size '1'	e. Shelf life:		aley it offit fight?			36	Months
if yes, enter class #			Orphan Drug Status			Size:			nitial shelf life at launch	(if different):			50	Months
a product kit?	No					Strength:	300 mg							_
if yes, list NDCs of			FDA Approval Status			ou engin.		-		ORDER INFOR	MATION			
component parts	N_					Dosage Form:	capsule				What is the	NDC selling	unit?	
reverse numbered? co-licensed?	No	_	Allergens Present						Init of Sale x Bottle			100 Capsules	-	
latex-free?	Yes	_	Allergens Fresent				CAPSULE	-	Box/Carton			.g. 1 Box of		
preservative-free?	Yes					Product Shape:			Ampule		(, .	5	,	
correctional institution block?	No					Product Color:	Yellow color cap/Yellow		Glass		Minimum o	rder quantit	y?	Yes
opioid?	No	_		111514		i iouuot oololi	color body	_	Tube					
Cannabinoid?	No No		Country of Origin	INDIA		Product Imprint:	SG on Cap and 180 on Body	_	Vial Liquid Sgl Vial Liquid Multi		lf Vac have	many of wh	ich package	4.000
If Unit Dose, is item bar coded to hospital scanning?	No		Is this product covered u	under the			Bouy	-	Vial Powder Sql		x x	Each	lich package	e type ?
If Unit Dose, indicate NDC here:	110		Trade Agreements Act (No			-	Vial Power Multi		~	Inner/Cartor	n/Pack	
			-		·				Other: Write In			Case		
-			FOR GENERIC DRUG PRO	ODUCTS										
											-			
					Au		uthorized Generic, other on fields are not applicable			ARMACY ORDER				
I. Orange Book Rating:						Secu	on neius are not applicable	Rec. seit unit to customer? Rx bining unit to pharmacy:						
II. Generic Equivalent to What Brand?: Neurontin (gabapentin) Capsules								Bottle x Each (Write-in, e.g. 1 Vial) Gram						
	DRI	JG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOI	RMATION			(write-iii, e.g. i	vidij			Milliliter		
				,										
Does supplier meet DSCSA defini	ition of manufacturer?		Yes		GLN:	850045940003			ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?														
If yes, select exemption:					GCP:	850045940]	Weight Lbs.		ions (US msr		Volume	Saleable #
Other exemption - Write in:			No					1. 17		Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's			No	_		riginal product irect from mfr?		Item/Each:	0.15	NA	6.30	3.20	#VALUE!	1000 Caps per Bottle
Has FDA granted waiver/exceptio			No	-		ce manufacturer for rep	ackaged product	Box/Carton/Bun	dle/					per bottle
If yes, attach documentation fro					i i o i i do do da		aonagoa produot	Inner Pack:						
								Case:	4.15	14.00	9 20	4.50	579.60	24 bottles
		GTIN	AND HIBCC PRODUCT IN	NFORMATION					4.15	14.00	3.20	4.50	575.00	per case
Colooble Unit of Measure	O-la -bla (0.71			Pallet:		48.00	54.00	40.00	103680.00	117 Cases
Saleable Unit of Measure	Saleable C		HIBCC			N-14 82619143010	Unit of Use GTIN-14 382619143010							per pallet
Box/Carton/Bundle/Inner Pack	100				003	02013143010	002010140010		COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case	24				203	82619143014								
x Pallet	6							Regular Cost			Vendor #:			
								Invoice Cost (W	AC) (\$)		Whsl. Code			
	-				-			As of date:			Fineline Co	ae:		
								AS UI Uale.						
								11			1			
1		A	ttach copy of SAFETY DAT	A SHEET (SD	S) or non hazar	d letter, PACKAGE INSE	RT, LABEL AND PHOTO OF	PRODUCT PACKAG	GING and BARCODE.					
*Please provide any additional inf	formation on page 2.	A	ttach copy of SAFETY DAT	A SHEET (SD	S) or non hazar		RT, LABEL AND PHOTO OF gnated Drop Ship Only.		GING and BARCODE.			Paul T	homas	

HDA

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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3									
	MATERIAL HAZ	ARD 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?	No No No	SDS Hazard Classification Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard							
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 No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:							
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	No	Is the product a NIOSH hazardous drug? No If yes, indicate which:							
c. DOT Hazard Class		Haza	Hazardous Waste Identification						
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics					
Is this product regulated for shipment by IATA?	No								
(if yes, answer a-e below and provide SDS)	INU		REGISTRY RESTRICTIONS						
a. UN/Identification Number									
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group		Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No						
e. Inhalation Hazard?	No								
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No						
Passenger Cargo Passenger & Cargo		Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No						
Is this a reportable quantity? No 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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:	No	Phone:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments IT IS NOT A REMS							
SP#		Registry:	No						
ADD'L STORAGE INFORMATION		Registry Program Contact Name:	DRODUCT	Phone:					
		Comments IT IS NOT A REMS	PRODUCI						
Is the Product Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) ARCOS Reportable? No If yes, indicate which:	No	RI Contact tel. # if product received damaged:							
Schedule No. Is it a scheduled listed chemical product?:	No	Is product returnable for credit:							
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy: https://creekwoo	odpharma.com/wp-content,	/uploads/2023/07/Return-Goods-					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Policy.pdf								
Restricted to retail pharmacy only:	Special regulations or returns requirements for this								
Restricted to hospital, clinics, and physician offices only:		product in certain states?							
Restricted from US territories? (explain in comments)		If so, which states? Other requirements? Comments?							
Comments:									
		DUS NOTES and/or Image of Product Barcode:							
	MISCELLANEC	TOS NOTES and/or image of Product Barcode:							



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete. Version 2021 Order Method for Designated Drop Ship Product Standard Order Receipt and Processing Purchase orders may be accepted by: Purchase order daily receipt cut off time by supplier a. EDI Yes Cut off time: Fax Number: b. Autofax Fax Number: Days c. Fax Shipping lead time of PO: Hours d. Phone only Phone No.: e. Supplier Web Site only Site Address: Ships same day for next day receipt: Minimum Order Quantity: Units Ships for second day receipt: Supplier's Customer Service Number: Ships regular ground for 3-10 days receipt: Contracted 3PL company / contact #: Name: Direct customer solutions (R & S) 1-800-655-7556 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: Monday Days of week overnight is available: Comments: Tuesday Wednesday Thursday Fridav Priority Overnight receipt available: **Class of Trade Restriction:** PO Receipt Cut off time: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Saturday Overnight receipt available: Restricted to retail pharmacy only: PO Receipt Cut off time: Restricted to hospital, clinics, and physician offices only: Phone: Phone #: Order receipt method: Fax: Restricted from US territories? (explain in comments) Fax #: Comments: EDI: Overnight Fees apply: Other fees apply: Other Data Information Required to Process PO: **Return Instructions** Patient Procedure Date: Contact # if product is received damaged: Physician Name: Is product returnable for credit: Physician/Clinic Phone # URL/Link to returns policy: Physician State License # Physician/Clinic DEA #: Special regulations or returns requirements for this product in certain states? Physician/Clinic Specialty: If so, which states? Other requirements? Comments? **Miscellaneous Notes:** ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?