

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

Version 2021						Introduction Type:	New Item] [x Final Version			Date:	08-14	1-2024
			PRODUCT INFORMAT	ION					SPECIAL HAND	DLING AND STO	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	DA/BLA (drug); PM	A/510(k)(med	device):	204	4989				emperature Range	Controlled Roon	n – between 2	0 and 25 C (6	68° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	118582565							0	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na 82619-142-01	me: G	Babapentin capsules, USP 100 m Unit of Use NDC:		s 82619-142-01	UPC: N382	2619142013		(write in) Notes					
Selling Unit NDC: UDI	NA		CVX Code:		02019-142-01	MVX Code: NA	2619142013		NOLES					
											- 10		NI	1
Description: White to Off white powder filled in size "3" hard gelatin capsules with opaque White colored cap and opaque White colored body imprinted "SG" on Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No											NO			
Active Ingredient(s): Gabapentin													110	1
3 (.)	b. Contact for t	emperature excursion qu	estions:											
URL for Additional Product Inform									lame:		SUJIT SAK			
Address:	1130 US 46 W				a	Address 2: Suite		Number:			551-303-9330			
City: Key Contact:	Parsippany Paul Thomas				State: Email:		07054	Group E-mail:			sujit@creekwoodpharma.com			
Phone Number:	1-732-344-022				Fax:	paul@creekwoodpl	IIdfffid.COM	c. Special regulations for product in any states?			No			
Product Therapeutic Classificatio		Anticonvulsan	t						Special returns requiremen		t?		No	
			-						poolar lotarilo roquirorilori	to for the produc	••			
	ADDITIO	NAL PRODUC	T INFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produc	d. Store product (unit of sale) upright? Yes					
The product is?			Is the Product	Direct-Ship C	Dnly			11 F	Protect product (unit of sa	ale) from light?			No	1
a legend device?	ĺ	No	Is the Product	Unit of Use	-	Size:	16mm	e. Shelf life:		, J			36	Months
if yes, enter class #			Orphan Drug Status			Size.		1	nitial shelf life at launch (if different):				Months
a product kit?		No				Strength:	100 mg							
if yes, list NDCs of component parts			FDA Approval Status				capsule			ORDER INFOR	MATION			
reverse numbered?		No				Dosage Form:	capsule	ı	Jnit of Sale		What is the	NDC selling	a unit?	
co-licensed?		No	Allergens Present						x Bottle			100 Capsules		
latex-free?		Yes				Product Shape:	CAPSULE		Box/Carton		(Write-in, e	e.g. 1 Box of	10 Vials)	
preservative-free?		Yes				r roudet onape.			Ampule					
correctional institution block?		No				Product Color:	white (white to off white)	-	Glass		Minimum o	order quantit	y?	Yes
opioid? Cannabinoid?		No No	Country of Origin	INDIA			SG;179	-	Tube Vial Liquid Sal					
If Unit Dose, is item bar coded to			Country of Origin			Product Imprint:	50,175	-	Vial Liquid Ogl		If Yes. how	many of wh	ich package	type?
hospital scanning?		No	Is this product covered u	inder the					Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No				Vial Power Multi			Inner/Carto	n/Pack	
									Other: Write In		3	Case		
			FOR GENERIC DRUG PRO	DUCTS										
					Au	thorized Generic *If A	uthorized Generic, other	PHARMACY ORDER / BILL UNIT						
L Orange Darah Batinga				- '	Au		on fields are not applicable							
I. Orange Book Rating: II. Generic Equivalent to What Bra	and?	Neurontin (gal	bapentin) Capsules					Rec. sell unit to customer? Rx billing unit to pharmacy: Bottle X						
							(Write-in, e.g. 1 Vial) Gram							
		DRUG SU	IPPLY CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION							Milliliter		
			X											
Does supplier meet DSCSA defini Is product exempt from DSCSA?	ition of manufacture	er?	Yes	-	GLN:	850045940003			IIEM	AND PACKING	INFORMATIO	N		
	l				CCD.	850045940		1		Dime	sions (US ms	mte)	Val	Calaatis #
If yes, select exemption: Other exemption - Write in:					GCP:	000045940		1	Weight Lbs.	Dimens	Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes, was or	iginal product		Item/Each:	0.0700			1		100 caps
Is product sold by manufacturer's	s exclusive distribu	tor?	No		purchased di	rect from mfr?			0.0726	NA	3.17	1.72	#VALUE!	per bottle
Has FDA granted waiver/exceptio		oduct?	No		Provide sour	ce manufacturer for rep	ackaged product	Box/Carton/Bui	ndle/					
If yes, attach documentation fro	m FDA.							Inner Pack:						
			GTIN AND HIBCC PRODUCT IN	FORMATION				Case:	2.204	12.40	8.40	4.40	458.304	24 bottles per case
								Pallet:						160 Cases
Saleable Unit of Measure	Sa	leable Quantit	y HIBCC		GTI	N-14	Unit of Use GTIN-14			48	54	40	103680	per Pallet
x Item/Each	[100			003	82619142013	382619142013							
Box/Carton/Bundle/Inner Pack								-	COST INFORMATION			WHOLESAL	ER USE ONI	_Y:
X Case		24			203	82619142017		Berular Cost			Vendor #:			
X Pallet	1 H	3						Regular Cost Invoice Cost (W	(AC) (\$)		Whsl. Cod	e #:		
									- / */		Fineline Co			
								As of date:						
] [
μ					· ·	11 / DAG// 05 / 12 -								
t Diana and da title			Attach copy of SAFETY DAT	A SHEET (SDS) or non hazar							- ·-	1	
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature: Paul Thomas														

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: No NFPA Storage Level: Image: Constraint of the 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? If yes, indicate which:							
c. DOT Hazard Class		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 PRODUCT							
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	RETURN INSTRUCTIONS 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:	Yes	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?