

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

Version 2021						Introduction Type:	New Item		x Fi	inal Version			Date:	09-23-	-2024	
			PRODUCT INFORMAT	ION						SPECIAL HAND	LING AND STOR	RAGE REQUI	REMENTS*			
								a Temperature	emperature – Indicate the USP temperature range for this product.							
				A2	213423	7.65.000.000.00	7.1.1571				Controlled Room	- between 20	and 25 C (38° – 77° F)		
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): Medical Device Class, if applicable: Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
DUNS:	118582565							1	Other Tem	perature Range I	Requirement					
Proprietary Name (If Applicable)		lame Prec	gabalin Capsules 25 mg					1	(write		rtequirement					
Selling Unit NDC:	82619-122-01	1.108	Unit of Use NDC:		82619-122-01	UPC: 3826	19122015		Notes	,,						
UDI	NA		CVX Code:		02010 122 01	MVX Code: NA	10122010		. 10100							
-	D 1 11 05	1 110:		1 4 1 20 1				1	1- 41-1			:0		NI-		
Description:	off- white crystalli		4" White, hard-gelatin capsule	e printed with t	black ink "CVV" o	on the cap, and "25" on tr	ie body containing white to				d to customers on			No	1	
Active Ingredient(s):	on- write crystall	Pregabalin							is this prod	uct to be snipped	d to customers on	ary ice?		No		
Active ingredient(s):		Pregabalin						h Contact for t	tomporatiu	re excursion qu	actions:					
URL for Additional Product Inform	mation:								Name:	e excursion qu	estions.	SUJIT SAKE	ΡΔΙ			
Address:	1130 US 46 W				I	Address 2: Suite	21		Number:			551-303-933				
City:	Parsippany				State:	NJ Zip		Group E-m	nail:		sujit@cree		arma.com			
Key Contact:	Paul Thomas				Email:	paul@creekwoodp										
Phone Number:	1-732-344-022				Fax:		c. Special regu	ulations for	product in any	states?			No	i		
Product Therapeutic Classification	on:	Anticonvulsant								-	ts for this product	?		No	l	
					_											
	ADDITIO	ONAL PRODUCT I	NFORMATION			PRODUCT DESCI	RIPTION INFORMATION	d. Store produ	ct (unit of	sale) upright?				No	l	
The product is?			Is the Product	Direct-Ship	Only			1 1		oduct (unit of sa	ale) from light?			No	1	
a legend device?		No	Is the Product	Unit of Use	Offiny		4	e. Shelf life:	Protect pro	bauct (unit of Sa	ale) from light?			24	Months	
if yes, enter class #		INU		Offic Of OSE		Size:	4		Initial chal	f life at launch (if different):			24	Months	
a product kit?		No	Orphan Drug Status				25 mg		illitiai Silei	i ille at laurich (ii uiiiereiitj.			24	WIOTILIS	
if yes, list NDCs of		INO	FDA Approval Status			Strength:	25 mg				ORDER INFORM	MATION				
component parts			1 DA Approvar Glatas				Capsules				O.1.5					
reverse numbered?		No				Dosage Form:	Сарошес		Unit of Sal	e		What is the	NDC selling	a unit?		
co-licensed?		No	Allergens Present							ottle		1 bottel of 9		,		
latex-free?		Yes	Ţ.				Caspule			ox/Carton			g. 1 Box of	10 Vials)		
preservative-free?		Yes				Product Shape:				mpule		,	•	,	Į.	
correctional institution block?		No				Draduct Calari	White, Printed with black		G	lass		Minimum o	rder quantit	y?	Yes	
opioid?		No				Product Color:			T	ube				-		
Cannabinoid?		No	Country of Origin	INDIA		Product Imprint:	"CW" on the cap		V	ial Liquid Sgl						
If Unit Dose, is item bar coded to	unit dose for					Froduct imprint.	and "25" on the body		V	ial Liquid Multi		If Yes, how	many of wh	nich package	type?	
hospital scanning?		No	Is this product covered u	ınder the					V	ial Powder Sql		48	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No				V	ial Power Multi			Inner/Carto	n/Pack	l.	
									0	ther: Write In		1	Case		Į.	
			FOR GENERIC DRUG PRO	DDUCTS												
					Au		uthorized Generic, other			PH/	ARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:						secti	on fields are not applicable	Rec. sell unit to	o custome	r?		Rx billing u	nit to pharn	пасу:		
II. Generic Equivalent to What Brand?: LYRICA							1 bottle of 90 capsules X Each					Į.				
								(Write-in, e.g. 1	1 Vial)				Gram		Ų	
		DRUG SUPP	PLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION								Milliliter		Ų	
Does supplier meet DSCSA defin	ition of manufact	ıror?	Yes		GLN:	850045940003				ITEM	AND PACKING II	NEORMATIO	J			
Is product exempt from DSCSA?	adon or manuracti	arer:	100		GLIN.	030043940003				— II EIVI	AND I ACKING II	A CINNATIO	•			
•						050045040					D:	(110	-4- \		.	
If yes, select exemption: Other exemption - Write in:					GCP:	850045940				Weight Lbs.	Dimensi	ions (US msn Width	nts.) Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?			No		If you was a	riginal product		Item/Each:						<u> </u>	1 leces	
Is product repackaged:	e avelusiva distrib	outor?	No	_		irect from mfr?		item/Lacii.		80.0	NA	1.57	2.95	4.63	1	
Has FDA granted waiver/exception			No	_		ce manufacturer for rep	ackaged product	Box/Carton/Bu	ındle/							
If yes, attach documentation fro							aumagea product	Inner Pack:								
• • • • • • • • • • • • • • • • • • • •								Case:		4.00	40.00	40.00	4.40	E00.00040	40	
		GT	TIN AND HIBCC PRODUCT IN	IFORMATION				1		4.82	12.99	10.03	4.13	538.09646	48	
								Pallet:		578.91	47.24	39.37	41.33	76867.138	120	
Saleable Unit of Measure	8	Saleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN-14			5/6.91	47.24	39.37	41.33	76867.138	120	
x Item/Each	1 00382619122015 382619122015 undle/Inner Pack															
Box/Carton/Bundle/Inner Pack							COST INFORMATION				WHOLESALER USE ONLY:					
Case		48			203	82619122019										
x Pallet	_	120						Regular Cost				Vendor #:				
								Invoice Cost (V	WAC) (\$)			Whsl. Code				
									_			Fineline Co	de:			
								As of date:							Ų	
															ļ	
Ц								Ш				1				
						II " BAG:::: 6= ":==	DT ADEL AND DUGGES	DDODUCT TITLE								
*Please provide any additional in			Attach copy of SAFETY DAT	A SHEET (SD	S) or non hazar		RT, LABEL AND PHOTO OF gnated Drop Ship Only.		AGING and Signature:					Thomas		



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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard Does the product have an Aerosol class? If yes, c. Contact Hazard? No d. Does this product require special clean-up instructions? No identify NFPA Storage Level: (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? Nο (if yes, answer a-e below and provide SDS) If ves. indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No EPA Hazardous Waste Code: Waste Characteristics Is this product regulated for shipment by IATA? No REMS or REGISTRY RESTRICTIONS (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? Nο c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Med Guide Required No Passenger Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: No RQ Threshold: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: No (if yes, identify method below) DEA #: Provider Name: NCPDP# Limited Quantity Site Enrollment Number assigned Consumer Commodity, ORM-D NPI #: by Supplier: Small Quantity (49 CFR 173.4) Special Permit; DOT-SP IT IS NOT A REMS PRODUCT Comments Special Provision (listed in Column 7 of 49 CFR 172.101); Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION IT IS NOT A REMS PRODUCT Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If ves. indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: Yes Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE: 02/13/2024



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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						
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier						
a. EDI	Yes	Cut off time:						
b. Autofax	Fax Number:							
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days						
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)							
	Phone: 1-800-655-7556							
Expedited Freight Ch	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order	er:	Overnight receipt available:						
Drop Ship service fee billed with each orde	er:	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:						
Cli	ass of Trade Restriction:	PO Receipt Cut off time:						
	pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:						
Restricted to retail pharmacy only:	briannacy, nospitals, clinics and physician offices	PO Receipt Cut off time:						
Restricted to hospital, clinics, and physicia	on offices only:	Phone:						
Restricted from US territories? (explain in		Order receipt method: Fax: Fax #:						
Comments:		EDI:						
		Overnight Fees apply:						
		Other fees apply:						
Other Data In	formation 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 #		one can to retain opensy.						
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?						
		is product order for restocking purposes:						