



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

Version 2021

Introduction Type: New Item☒ Final Version

Date: 09/22/2026

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: CREEKWOOD PHARMACEUTICALS LLC Application: ANDA				a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A213423				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in)			
DUNS: 118582565				Notes			
Proprietary Name (If Applicable) and Established Name: Pregabalin Capsules 100 mg				Is this product to be shipped to customers on ice? No			
Selling Unit NDC: 82619-125-01 Unit of Use NDC: 82619-125-01 UPC: 382619125016				Is this product to be shipped to customers on dry ice? No			
UDI: NA CVX Code: MVX Code: NA				b. Contact for temperature excursion questions:			
Description: Pregabalin 100mg capsules are "Size 3" Orange, hard-gelatin capsule printed with black ink "CW" on the cap, and "100" on the body containing white to off-white crystalline powder.				Name: SUJIT SAKPAL			
Active Ingredient(s): Pregabalin				Number: 551-303-9330			
URL for Additional Product Information:				Group E-mail: sujit@creekwoodpharma.com			
Address: 1130 US 46 W				Address 2: Suite 21			
City: Parsippany				State: NJ Zip: 07054			
Key Contact: Paul Thomas				Email: paul@creekwoodpharma.com			
Phone Number: 1-732-344-022				Fax:			
Product Therapeutic Classification: Anticonvulsant				c. Special regulations for product in any states?			
				Special returns requirements for this product? No			
				d. Store product (unit of sale) upright?			
				Protect product (unit of sale) from light? No			
				e. Shelf life:			
				Initial shelf life at launch (if different): 24 Months			
				24 Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		Strength:	
a legend device? No		Direct-Ship Only		3		100mg	
if yes, enter class #		Is the Product...					
a product kit? No		Orphan Drug Status					
if yes, list NDCs of component parts		FDA Approval Status		Dosage Form:		Capsules	
reverse numbered? No		Allergens Present		Product Shape:		Capsule	
co-licensed? No		Country of Origin INDIA		Product Color:		Orange, Printed with black ink	
latex-free? Yes		Is this product covered under the Trade Agreements Act (TAA)? No		Product Imprint:		"CW" on the cap and "100" on the body	
preservative-free? Yes							
correctional institution block? No							
opioid? No							
Cannabinoid? No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? No							
If Unit Dose, indicate NDC here:							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: ☐ Authorized Generic *If Authorized Generic, other section fields are not applicable							
II. Generic Equivalent to What Brand?: LYRICA							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes				GLN: 850045940003			
Is product exempt from DSCSA?				GCP: 850045940			
If yes, select exemption:				If yes, was original product purchased direct from mfr?			
Other exemption - Write in:				Provide source manufacturer for repackaged product			
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.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14		
☒ Item/Each		1		00382619125016	00382619125016		
☒ Box/Carton/Bundle/Inner Pack		48		20382619125010			
☒ Case		5760					
☒ Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.08	NA	1.57	2.95	4.63	1	
Box/Carton/Bundle/Inner Pack:							
Case:	5.25	12.99	10.03	4.13	538.09646	48	
Pallet:	630.35	47.24	39.37	41.33	76867.138	5760	
COST INFORMATION							
Regular Cost				WHOLESALE USE ONLY:			
Invoice Cost (WAC) (\$)				Vendor #:			
				Whsl. Code #:			
As of date:				Fineline Code:			

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

Paul Thomas



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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? ☐ No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? ☐ No Is the product a CA Prop 65 reproductive toxicant? ☐ No Does the product label bear a CA Prop 65 warning? ☐ No c. Contact Hazard? ☐ No d. Does this product require special clean-up instructions? ☐ No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? ☐ No Is this product regulated for shipment by DOT? ☐ No (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? ☐ No Is this product regulated for shipment by IATA? ☐ No (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? ☐ No Is the product restricted for air shipment? If so, indicate restriction: ☐ Passenger ☐ Cargo ☐ Passenger & Cargo 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) ☐ Special Permit; DOT-SP ☐ Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		SDS Hazard Classification ☐ Organic ☐ Corrosive ☐ Inorganic ☐ Oxidizer # ☐ Steroid/Androgen ☐ Contact Hazard Does the product have an Aerosol class? If yes, ☐ No identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? ☐ No If yes, indicate which:	
Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics			
REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? ☐ No Website URL: Med Guide Required ☐ No Limited Distribution Requirement ☐ No Comments / Details: (For example, iPledge program?) REMS: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: ☐ No Wholesale distributor support: ☐ Provider Name: DEA #: Site Enrollment Number assigned by Supplier: NCPDP#: NPI #: Comments IT IS NOT A REMS PRODUCT Registry: Registry Program Contact Name: Phone: Comments IT IS NOT A REMS PRODUCT			
ADD'L STORAGE INFORMATION Is the Product... Controlled Substance? ☐ No Controlled Substance Code Controlled by State(s)? ☐ No Listed Chemical (List I or II) ☐ No ARCOS Reportable? ☐ No If yes, indicate which: Schedule No. 5 Is it a scheduled listed chemical product?: ☐ Yes			
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices ☐ Yes 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:			



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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: <table border="0"><tr><td>a. EDI</td><td>☐</td><td>Fax Number:</td><td> </td></tr><tr><td>b. Autofax</td><td>☐</td><td>Fax Number:</td><td> </td></tr><tr><td>c. Fax</td><td>☐</td><td>Pregabalin Caps</td><td> </td></tr><tr><td>d. Phone only</td><td>☐</td><td>Site Address:</td><td> </td></tr><tr><td>e. Supplier Web Site only</td><td>☐</td><td></td><td></td></tr></table> Minimum Order Quantity: Units Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Direct customer solutions (R & S) Phone: 1-800-655-7556	a. EDI	☐	Fax Number:		b. Autofax	☐	Fax Number:		c. Fax	☐	Pregabalin Caps		d. Phone only	☐	Site Address:		e. Supplier Web Site only	☐			Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships for second day receipt: Ships regular ground for 3-10 days receipt:
a. EDI	☐	Fax Number:																			
b. Autofax	☐	Fax Number:																			
c. Fax	☐	Pregabalin Caps																			
d. Phone only	☐	Site Address:																			
e. Supplier Web Site only	☐																				
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																				
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: <table border="0"><tr><td>☐</td><td>Monday</td></tr><tr><td>☐</td><td>Tuesday</td></tr><tr><td>☐</td><td>Wednesday</td></tr><tr><td>☐</td><td>Thursday</td></tr><tr><td>☐</td><td>Friday</td></tr></table> Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:	☐	Monday	☐	Tuesday	☐	Wednesday	☐	Thursday	☐	Friday										
☐	Monday																				
☐	Tuesday																				
☐	Wednesday																				
☐	Thursday																				
☐	Friday																				
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:																					
Other Data Information Required to Process PO:	Return Instructions																				
Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Contact # if product is 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?																				
Miscellaneous Notes:	ADDITIONAL INFORMATION																				
	Is product order for scheduled patient procedure? Is product order for restocking purposes?																				