

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

Version 2021							Introduction Type:	New Item	X	Final Version			Date:	09-23-	-2024
			P	RODUCT INFORMAT	ION				•	SPECIAL HANI	DLING AND STOP	AGE REQUI	REMENTS*		
Company Name:	CREEKWOOD P	PHARMACEUT	FICALS LLC				Application:	ANDA	a. Temperature – Ind	icate the USP temp	erature range for	this product			
Application Number for NDA/AN					A213423					erature Range	Controlled Room			68° – 77° F)	
Medical Device Class, if applica										0					
DUNS:	118582565								Other <sup>-</sup>	Temperature Range	Requirement				
Proprietary Name (If Applicable)	and Established N	lame:	Pregabalin C	Capsules 75 mg					] (	write in)					
Selling Unit NDC:	82619-124-01			Unit of Use NDC:	8261	9-124-01	UPC: 3826	19124019	Notes						
UDI	NA			CVX Code:			MVX Code: NA								
Description:	Pregabalin 75mg	capsules are	"Size 4" White	e body and orange car	hard-gelatin capsul	e printed	with black ink "CW" on th	e cap, and "75" on the	Is this	product to be shippe	d to customers or	ice?		No	
	body containing				, g					product to be shippe				No	
Active Ingredient(s):		Pregabalin													
b. Contact for temperature excursion questions:															
URL for Additional Product Inform									Name:			SUJIT SAKE			
Address:	1130 US 46 W						Address 2: Suite		Numb			551-303-933			
City:	Parsippany State: NJ						07054	Group E-mail: <u>sujit@creekwoodpharma.com</u>					irma.com		
Key Contact:						paul@creekwoodph	arma.com	c. Special regulations for product in any states? No					Nia		
Phone Number:	1-732-344-022					Fax:						_		No	
Product Therapeutic Classification	on:	Anticonvuls	ant						Specia	I returns requiremen	ts for this product	?		No	
		ONAL PRODU		ATION				DTION INFORMATION							
	ADDITI	ONAL PRODU					PRODUCT DESCR	IPTION INFORMATION	d. Store product (uni					No	
The product is?				the Product	Direct-Ship Only					t product (unit of s	ale) from light?			No	
a legend device?		No		the Product	Unit of Use	_	Size:	4	e. Shelf life:					24	Months
if yes, enter class #			Or	phan Drug Status					Initial	shelf life at launch	if different):			24	Months
a product kit?		No		A Annual Clarker			Strength:	75 mg			ORDER INFORM				
if yes, list NDCs of component parts			FD	A Approval Status				Canquilar			ORDER INFORM	ATION			
reverse numbered?		No					Dosage Form:	Capsules	Unit of	f Sale		What is the	NDC selling	unit?	
co-licensed?		No	All	ergens Present					x	Bottle		1 bottel of 9		,	
latex-free?		Yes	-					Caspule	~	Box/Carton		(Write-in, e		0 Vials)	
preservative-free?		Yes	1				Product Shape:			Ampule		(	5	,	
correctional institution block?	•	No					Product Color:	White body and Orange c		Glass		Minimum o	der quantit	y?	Yes
opioid?		No					Product Color:			Tube				-	
Cannabinoid?		No	Co	ountry of Origin	INDIA		Product Imprint:	"CW" on the cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		-					and "75" on the body		Vial Liquid Multi				ich package	type?
hospital scanning?		No		this product covered u						Vial Powder Sql		48	Each		
If Unit Dose, indicate NDC here:			Ira	ade Agreements Act (1	AA)? No					Vial Power Multi			Inner/Cartor	1/Pack	
										Other: Write In		1	Case		
			FOR	GENERIC DRUG PRO	DUCTS				_						
						A + 1	horized Generic *If Au	thorized Generic, other		DH	ARMACY ORDER				
						Auti		on fields are not applicable							
I. Orange Book Rating:	10								Rec. sell unit to cust		1	Rx billing u		acy:	
II. Generic Equivalent to What Brand?: LYRICA						1 bottle of 90 capsules         X         Each           (Write-in, e.g. 1 Vial)         Gram				Each					
		DRUG S	SUPPLY CHA	IN SECURITY ACT (D	SCSA) INFORMATIO	DN			(write-in, e.g. 1 viai)				Milliliter		
		511001										I	Winniton		
Does supplier meet DSCSA defin	nition of manufact	urer?		Yes	GLN:		850045940003			ITEM	AND PACKING I	NFORMATION	I		
Is product exempt from DSCSA?															
If yes, select exemption:					GCP		850045940		1		Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:					GCF.		0000000		1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	)	lf ves	, was ori	ginal product		Item/Each:	0.07				<u>, ,</u>	
Is product sold by manufacturer			1	No			ect from mfr?			0.07	NA	1.57	2.95	4.63	1
	's exclusive distri	Sutor?													
nas ruk granieu waiver/exceptic	on/exemption for j			No	Prov	de sourc	e manufacturer for repart	ackaged product	Box/Carton/Bundle/						
If yes, attach documentation fro	on/exemption for p			No	Prov	de sourc	e manufacturer for repa	ackaged product	Box/Carton/Bundle/ Inner Pack:						48
	on/exemption for p					de sourc	e manufacturer for repa	ackaged product		4.82	12.99	10.03	4 13	538 09646	
	on/exemption for p		GTIN AND	No HIBCC PRODUCT IN		de sourc	e manufacturer for repa	ackaged product	Inner Pack: Case:	4.82	12.99	10.03	4.13	538.09646	
If yes, attach documentation fro	on/exemption for p om FDA.	product?		HIBCC PRODUCT IN					Inner Pack:		12.99	10.03			120
If yes, attach documentation fro Saleable Unit of Measure	on/exemption for pom FDA.	product? Saleable Quan				GTIN	I-14	Unit of Use GTIN-14	Inner Pack: Case:	4.82			4.13 41.33	538.09646 76867.138	120
If yes, attach documentation fro	on/exemption for pom FDA.	product?		HIBCC PRODUCT IN		GTIN			Inner Pack: Case: Pallet:	578.91		39.37	41.33	76867.138	
If yes, attach documentation fro	on/exemption for pom FDA.	Saleable Quan		HIBCC PRODUCT IN		GTIN 0038	I-14 2619124019	Unit of Use GTIN-14	Inner Pack: Case: Pallet:			39.37	41.33		
If yes, attach documentation fro	on/exemption for pom FDA.	Saleable Quan		HIBCC PRODUCT IN		GTIN 0038	I-14	Unit of Use GTIN-14	Inner Pack: Case: Pallet: CO	578.91		39.37	41.33	76867.138	
If yes, attach documentation fro	on/exemption for pom FDA.	Saleable Quan		HIBCC PRODUCT IN		GTIN 0038	I-14 2619124019	Unit of Use GTIN-14	Inner Pack: Case: Pallet: CO Regular Cost	578.91 ST INFORMATION		39.37 Vendor #:	41.33 VHOLESAL	76867.138	
If yes, attach documentation fro Saleable Unit of Measure X hem/Each Box/Carton/Bundle/Inner Pack Case	on/exemption for pom FDA.	Saleable Quan		HIBCC PRODUCT IN		GTIN 0038	I-14 2619124019	Unit of Use GTIN-14	Inner Pack: Case: Pallet: CO	578.91 ST INFORMATION		39.37	41.33 VHOLESAL #:	76867.138	
If yes, attach documentation fro Saleable Unit of Measure X hem/Each Box/Carton/Bundle/Inner Pack Case	on/exemption for pom FDA.	Saleable Quan		HIBCC PRODUCT IN		GTIN 0038	I-14 2619124019	Unit of Use GTIN-14	Inner Pack: Case: Pallet: CO Regular Cost	578.91 ST INFORMATION		39.37 Vendor #: Whsl. Code	41.33 VHOLESAL #:	76867.138	
If yes, attach documentation fro Saleable Unit of Measure X hem/Each Box/Carton/Bundle/Inner Pack Case	on/exemption for pom FDA.	Saleable Quan		HIBCC PRODUCT IN		GTIN 0038	I-14 2619124019	Unit of Use GTIN-14	Inner Pack: Case: Pallet: CO Regular Cost Invoice Cost (WAC) (	578.91 ST INFORMATION		39.37 Vendor #: Whsl. Code	41.33 VHOLESAL #:	76867.138	
If yes, attach documentation fro Saleable Unit of Measure X hem/Each Box/Carton/Bundle/Inner Pack Case	on/exemption for pom FDA.	Saleable Quan		HIBCC PRODUCT IN		GTIN 0038	I-14 2619124019	Unit of Use GTIN-14	Inner Pack: Case: Pallet: CO Regular Cost Invoice Cost (WAC) (	578.91 ST INFORMATION		39.37 Vendor #: Whsl. Code	41.33 VHOLESAL #:	76867.138	
If yes, attach documentation fro Saleable Unit of Measure X hem/Each Box/Carton/Bundle/Inner Pack Case	on/exemption for pom FDA.	Saleable Quan		HIBCC PRODUCT IN BCC	FORMATION	GTIN 0038 2038	L-14 2619124019 2619124013	Unit of Use GTIN-14	Inner Pack: Case: Pallet: CO Regular Cost Invoice Cost (WAC) ( As of date:	578.91 ST INFORMATION \$)		39.37 Vendor #: Whsl. Code	41.33 VHOLESAL #:	76867.138	
If yes, attach documentation fro Saleable Unit of Measure X hem/Each Box/Carton/Bundle/Inner Pack Case	on/exemption for p om FDA.	Saleable Quan		HIBCC PRODUCT IN BCC	FORMATION	GTIN 0038 2038	L-14 2619124019 2619124013	Unit of Use GTIN-14 382619124019	Inner Pack: Case: Pallet: CO Regular Cost Invoice Cost (WAC) ( As of date:	578.91 ST INFORMATION S) and BARCODE.		39.37 Vendor #: Whsl. Code	41.33 VHOLESAL #: de:	76867.138	

## HDA

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

Version 2021 For Designated Drop Ship Only Products, Please Use Page 3								
TAM	ERIAL HAZAR	D 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						
<ul> <li>c. Contact Hazard?</li> <li>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)</li> <li>e. Does the product contain DEHP?</li> </ul>	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	No					
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 c. DOT Hazard Class	No	Is the product a NIOSH hazardous drug? If yes, indicate which: Hazar	No dous Waste Identification					
d. Packing Group		EDA Hazardava Wasta Cada	Waste Characteristics					
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics					
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No	REMS or	REGISTRY RESTRICTIONS					
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Deding Crown		Is there a REMS on this product? Website URL:	No					
d. Packing Group e. Inhalation Hazard?	No	Website URL:						
Is the product restricted for air shipment? If so, indicate restriction:           Passenger           Cargo           Passenger & Cargo		Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No 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:           DEA #:         NCPDP#:           NPI #:         NPI #:					
Special Perovision (listed in Column 7 of 49 CFR 172.101);		Comments IT IS NOT A REMS	PRODUCT					
SP#		Registry: Registry Program Contact Name:	No Phone:					
ADD'L STORAGE INFORMATION		Comments IT IS NOT A REMS I	PRODUCT					
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: Schedule No. 5 Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	No Yes	Contact tel. # if product received damaged: Is product returnable for credit:	TURN INSTRUCTIONS					
	Yes	Policy.pdf						
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)		Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
Comments:								
MIS		S NOTES and/or Image of Product Barcode:						
	OLLEANEOUS	to the analog in router barcoue.						



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

Version 2021 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: Fax Number: b. Autofax Days c. Fax Fax Number: Shipping lead time of PO: Hours d. Phone only Pregabalin Caps e. Supplier Web Site only Site Address: 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 #: Direct customer solutions (R & S) Name: 1-800-655-7556 Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: **Overnight and Priority Overnight PO Processing** Overnight receipt available: Expedited freight fees billed with each order: 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 Wednesdav 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: Restricted from US territories? (explain in comments) Fax: Fax #: EDI: Comments: 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?