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

Version 2021 | Introduction Type: New Item | x Final Version | Date: 09-23-2024

PRODUCT INFORMATION

Company Name:	CREEKWOOD PHARMACEUTICALS LLC			**Application:**	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	A213423				
Medical Device Class, if applicable:					
DUNS:	118582565				
Proprietary Name (If Applicable) and Established Name:	Pregabalin Capsules 200 mg				
Selling Unit NDC:	82619-127-01	**Unit of Use NDC:**	82619-127-01	**UPC:**	**382619127010**
UDI	NA	**CVX Code:**		**MVX Code:**	**NA**
Description:	Pregabalin 200mg capsules are"Size 1" Light Orange, hard-gelatin capsule printed with black ink "CW" on the cap, and "200" on the body containing white to off- white crystalline powder.				
Active Ingredient(s):	Pregabalin				
URL for Additional Product Information:					
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				

ADDITIONAL PRODUCT INFORMATION

The product is?		**Is the Product…**	Direct-Ship Only
a legend device?	No	**Is the Product…**	Unit of Use
if yes, enter class #		**Orphan Drug Status**	
a product kit?	No		
if yes, list NDCs of component parts		**FDA Approval Status**	
reverse numbered?	No		
co-licensed?	No	**Allergens Present**	
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No	Country of Origin	INDIA
If Unit Dose, is item bar coded to unit dose for hospital scanning?	No	Is this product covered under the Trade Agreements Act (TAA)?	No
If Unit Dose, indicate NDC here:			

PRODUCT DESCRIPTION INFORMATION

Size:	1
Strength:	200 mg
Dosage Form:	Capsules
Product Shape:	Caspule
Product Color:	Light Orange,printed with black ink
Product Imprint:	"CW" on the cap, and "200" on the body

FOR GENERIC DRUG PRODUCTS

		Authorized Generic	*If Authorized Generic, other section fields are not applicable
I. Orange Book Rating:			
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?			
If yes, select exemption:		**GCP:**	850045940
Other exemption - Write in:			
Is product repackaged?	No	**If yes, was original product purchased direct from mfr?**	
Is product sold by manufacturer's exclusive distributor?	No		
Has FDA granted waiver/exception/exemption for product?	No	**Provide source manufacturer for repackaged product**	
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
x	Item/Each	1		00382619127010	382619127010
	Box/Carton/Bundle/Inner Pack				
x	Case	24		20382619127014	
x	Pallet	120			

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No

b. Contact for temperature excursion questions:

Name:	SUJIT SAKPAL
Number:	551-303-9330
Group E-mail:	sujit@creekwoodpharma.com

c. Special regulations for product in any states?	No	
Special returns requirements for this product?	No	
d. Store product (unit of sale) upright?	No	
Protect product (unit of sale) from light?	No	
e. Shelf life:	24	**Months**
Initial shelf life at launch (if different):	24	**Months**

ORDER INFORMATION

	Unit of Sale
x	Bottle
	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sql
	Vial Power Multi
	Other: Write In

What is the NDC selling unit? 1 bottel of 90 Capsules (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

24	Each
	Inner/Carton/Pack
1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 bottle of 90 capsules (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

X	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.13	NA	1.87	3.77	7.05	1
Box/Carton/Bundle/ Inner Pack:						
Case:	4.14	11.61	7.87	4.96	453.19867	24
Pallet:	496.46	47.24	39.37	39.68	73798.404	120

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	
As of date:	

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

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

***Please provide any additional information on page 2.** **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? (If yes, attach SDS with special instructions.)	No
e. Does the product contain DEHP?	No
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	No
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? (if yes, answer a-e below and provide SDS)	No
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:	No

- ☐ 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, identify NFPA Storage Level:	No
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:	No
REMS Program Manager Name:	Phone:
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	DEA #:
Site Enrollment Number assigned by Supplier:	NCPDP#: / NPI #:
Comments	IT IS NOT A REMS PRODUCT
Registry:	No
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.		Is it a scheduled listed chemical product?:	No

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:	

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:	
Is product returnable for credit:	
URL/Link to returns policy:	https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf
Special regulations or returns requirements for this product in certain states?	
If so, which states? Other requirements? 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

Purchase orders may be accepted by:

a. EDI	Yes		
b. Autofax		Fax Number:	
c. Fax		Fax Number:	
d. Phone only			
e. Supplier Web Site only		Site Address:	

Minimum Order Quantity: Units

Supplier's Customer Service Number:

Contracted 3PL company / contact #: Name: Direct customer solutions (R & S)

Phone: 1-800-655-7556

Standard Order Receipt and Processing

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:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

Days of week overnight is available:

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

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:

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:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Return Instructions

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?