



Date: 08-14-2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name:		CREEKWOOD PHARMACEUTICALS LLC		Application:		ANDA	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):		A219460					
Medical Device Class, if applicable:							
DUNS:	118582565						
Proprietary Name (if Applicable) and Established Name:		Propranolol Extended Release Capsule USP, 120mg					
Selling Unit NDC:	82619-134-02	Unit of Use NDC:	82619-134-02	UPC:	382619134025		
UDI	NA	CVX Code:		MVX Code:	NA		
Description:		Light blue opaque body and Dark blue opaque cap, size "2" hard gelatin capsule imprinted with "327" on cap and "120" on body in black ink, filled with white to off white spherical pellets.					
Active Ingredient(s):		Propranolol Hydrochloride					
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:		Anti Hypertensive					
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?							
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):						Months	
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?				Size:		15.8mm	
a legend device?	☐ No	Is the Product...	☐ Direct-Ship Only	Strength:		120mg	
if yes, enter class #		Is the Product...	☐ Unit of Use	Dosage Form:		Capsules	
a product kit?	☐ No	Orphan Drug Status		Product Shape:		Capsule shape	
if yes, list NDCs of component parts		FDA Approval Status		Product Color:		Light blue and Dark blue (opaque)	
reverse numbered?	☐ No	Allergens Present		Product Imprint:		"327" on cap and "120" on body in black ink	
co-licensed?	☐ No	Country of Origin	INDIA				
latex-free?	☒ Yes						
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	Is this product covered under the Trade Agreements Act (TAA)?		☐ 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?:		Inderal LA					
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:							
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	
☒ Item/Each		1				00382619134025	Unit of Use GTIN-14
☐ Box/Carton/Bundle/Inner Pack							382619134025
☒ Case		60				20382619134029	
☒ Pallet		64					
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer?				Rx billing unit to pharmacy:			
☐ Bottles 500 count				☒ Each			
(Write-in, e.g. 1 Vial)				☐ Gram			
				☐ Milliliter			
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)					



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

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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 Pregabalin Capsules 75 mg No Does the product label bear a CA Prop 65 warning? No c. Contact Hazard? No d. Does this Pregabalin 75mg capsules are "Size 4" White body and orange cap, hard-gel (If yes, attach SDS with special instructions.) No 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 4 Is there a REMS on this product? No 75 mg Website URL: Med Guide Required No Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) White body and Orange cap, printed with black ink REMS 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:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			



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

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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>Yes</td></tr><tr><td>b. Autofax</td><td>☐</td><td></td></tr><tr><td>c. Fax</td><td>☐</td><td></td></tr><tr><td>d. Phone only</td><td>☐</td><td></td></tr><tr><td>e. Supplier Web Site on 82619-124-01</td><td>☐</td><td></td></tr></table> Minimum Order Quantity: Units Supplier's Customer Service Number: Contracted 3PL company / c Pregabalin 75n Name: Direct customer solutions (R & S) Phone: 1-800-655-7556	a. EDI	☐	Yes	b. Autofax	☐		c. Fax	☐		d. Phone only	☐		e. Supplier Web Site on 82619-124-01	☐		Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days 82619-124-01 3.826E+11 Ships for second day receipt: Ships regular ground for 3-10 days receipt:
a. EDI	☐	Yes														
b. Autofax	☐															
c. Fax	☐															
d. Phone only	☐															
e. Supplier Web Site on 82619-124-01	☐															
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: White body and Orange cap, printed with black 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? ☐															