



Introduction Type:

Date: 09/22/2026

PRODUCT INFORMATION			
Company Name:		CREEKWOOD PHARMACEUTICALS LLC	
Application Number for NDA/ANDA/BLA; PMA/510(k):		A218162	
Medical Device Class, if applicable:			
DUNS:		118582565	
Proprietary Name (If Applicable) and Established Name:		Haloperidol Tablets USP 10 mg	
Selling Unit NDC:		82619-109-02	
UDI		Unit of Use NDC: 82619-109-02 CVX Code: UPC: 382619109023 MVX Code:	
Description: Pale pink, round shaped flat faced beveled edge uncoated tablets scored on one side and debossed with '301' on other side			
Active Ingredient(s):		Haloperidol USP	
URL for Additional Product Information:			
Address:		1130 US 46 W	
City:		Parsippany	
Key Contact:		Paul Thomas	
Phone Number:		1-732-344-0222	
Product Therapeutic Classification:		Antipsychotic	
Address 2:		Suite 21	
State:		NJ	
Email:		paul@creekwoodpharma.com	
Fax:		Zip: 07054	

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?	No	Is the Product... Direct-Ship Only	Size: 9.5 mm
a legend device?		Is the Product... Unit of Use	Strength: 10 mg
if yes, enter class #		Orphan Drug Status	Dosage Form: Tablet
a product kit?	No	FDA Approval Status	Product Shape: Round shaped
if yes, list NDCs of component parts		Allergens Present	Product Color: Pale Pink
reverse numbered?	No	Not present	Product Imprint: 301
co-licensed?	No	Country of Origin	INDIA
latex-free?	Yes	Is this product covered under the Trade Agreements Act (TAA)?	No
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:	AB
II. Generic Equivalent to What Brand?:	Haldol
Authorized Generic	
*If Authorized Generic, other section fields are not applicable	

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	
If yes, select exemption:	
Other exemption - Write in:	
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.	
GLN:	850045940003
GCP:	850045940
If yes, was original product purchased direct from mfr?	
Provide source manufacturer for repackaged product	

GTIN AND HIBCC PRODUCT INFORMATION					
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x Item/Each		1		00382619109023	00382619109023
Box/Carton/Bundle/Inner Pack					
x Case		60		20382619109027	
x Pallet		5760			

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?	
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:	36 Months
Initial shelf life at launch (if different):	36 Months

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
x Bottle	1 bottle of 100 Tablets
Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
Ampule	
Glass	Minimum order quantity? Yes
Tube	
Vial Liquid Sgl	
Vial Liquid Multi	If Yes, how many of which package type?
Vial Powder Sgl	60 Each
Vial Power Multi	Inner/Carton/Pack
Other: Write In	1 Case

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 bottle of 100 tablets	x Each
(Write-in, e.g. 1 Vial)	Gram
HCPCS J-Code:	Milliliter

ITEM AND PACKING INFORMATION						
Weight Lbs.	Dimensions (US msmts.)	Volume (Cube)	Saleable # Pieces			
Depth	Width	Height				
Item/Each:	0.1	1.56	2.95	4.60	1	
Box/Carton/Bundle/ Inner Pack:						
Case:	6.48	10.03	8.46	8.07	684.77	60
Pallet:	622.39	40.15	33.85	48.42	65806.53	5760

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		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:



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 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 <table><tr><td>☐ Organic</td><td>☐ Corrosive</td></tr><tr><td>☐ Inorganic</td><td>☐ Oxidizer</td></tr><tr><td>☐ Steroid/Androgen</td><td>☐ Contact Hazard</td></tr></table> Does the product have an Aerosol class? If yes, identify No NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? No If yes, indicate which:		☐ Organic	☐ Corrosive	☐ Inorganic	☐ Oxidizer	☐ Steroid/Androgen	☐ Contact Hazard										
☐ Organic	☐ Corrosive																		
☐ Inorganic	☐ Oxidizer																		
☐ Steroid/Androgen	☐ Contact Hazard																		
Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics																			
REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL: Med Guide Required No Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: DEA #: NCPDP#: NPI #: Comments IT IS NOT A REMS PRODUCT Registry: Registry Program Contact Name: Comments IT IS NOT A REMS PRODUCT																			
ADD'L STORAGE INFORMATION Is the Product... <table><tr><td>Controlled Substance?</td><td> No </td><td>Controlled Substance Code</td><td> </td></tr><tr><td>Controlled by State(s)?</td><td> No </td><td>Listed Chemical (List I or II)</td><td> No </td></tr><tr><td>ARCOS Reportable?</td><td> No </td><td>If yes, indicate which:</td><td> </td></tr><tr><td>Schedule No.</td><td> </td><td>Is it a scheduled listed chemical product?:</td><td> No </td></tr></table>				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
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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:																			

Release DATE



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: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Direct customer solutions (R & S) Phone: 1-800-655-7556	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: 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?