



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION	SPECIAL HANDLING AND STORAGE REQUIREMENTS*
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Company Name: CREEKWOOD PHARMACEUTICALS LLC **Application:** ANDA

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A218673

Medical Device Class, if applicable:

DUNS: 118582565

Proprietary Name (If Applicable) and Established Name: Metformin Hydrochloride Extended-Release Tablets, USP 500mg, 500 tablets per bottle

Selling Unit NDC: 82619-140-02 **Unit of Use NDC:** 82619-140-02 **UPC:** 382619140026

UDI: NA **CVX Code:** **MXV Code:** NA

Description: Metformin Hydrochloride Extended-Release Tablets, USP 500mg, 500 tablets per bottle
[White to off white, oval (Modified Capsule) shaped tablet debossed with "M16" on one side and plain on another side. Tablets should be free from

Active Ingredient(s): Metformin Hydrochloride API

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-hyperglycemic

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement (write in):
 Notes:

Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?

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?

d. Store product (unit of sale) upright?
Protect product (unit of sale) from light?

e. Shelf life: Months
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
<p>The product is a legend device? <input type="text" value="No"/></p> <p>if yes, enter class #</p> <p>a product kit? <input type="text" value="No"/></p> <p>if yes, list NDCs of component parts reverse numbered?</p> <p>co-licensed? <input type="text" value="No"/></p> <p>latex-free? <input type="text" value="Yes"/></p> <p>preservative-free? <input type="text" value="Yes"/></p> <p>correctional institution block? <input type="text" value="Yes"/></p> <p>opioid? <input type="text" value="No"/></p> <p>Cannabinoid? <input type="text" value="No"/></p> <p>If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text" value="No"/></p> <p>If Unit Dose, indicate NDC here:</p>	<p>Is the Product... Direct-Ship Only <input type="text" value=""/></p> <p>Is the Product... Unit of Use <input type="text" value=""/></p> <p>Orphan Drug Status <input type="text" value=""/></p> <p>FDA Approval Status <input type="text" value=""/></p> <p>Allergens Present <input type="text" value="NA"/></p> <p>Country of Origin <input type="text" value="INDIA"/></p> <p>Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/></p>
	<p>Size: <input type="text" value="100"/></p> <p>Strength: <input type="text" value="500mg"/></p> <p>Dosage Form: <input type="text" value="Tablets"/></p> <p>Product Shape: <input type="text" value="Oval (Modified Capsule) shaped"/></p> <p>Product Color: <input type="text" value="White to off-white"/></p> <p>Product Imprint: <input and"="" m16"="" on="" one="" side="" type="text" value="Debossed with "/></p>

ORDER INFORMATION

Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In	What is the NDC selling unit? <input type="text" value="1 bottle of 500 Tablets"/> (Write-in, e.g. 1 Box of 10 Vials)						
	Minimum order quantity? <input type="text" value="Yes"/>						
	If Yes, how many of which package type? <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td><input type="text" value="12"/></td> <td>Each</td> </tr> <tr> <td><input type="text" value="1"/></td> <td>Inner/ Carton/Pack</td> </tr> <tr> <td><input type="text" value="1"/></td> <td>Case</td> </tr> </table>	<input type="text" value="12"/>	Each	<input type="text" value="1"/>	Inner/ Carton/Pack	<input type="text" value="1"/>	Case
<input type="text" value="12"/>	Each						
<input type="text" value="1"/>	Inner/ Carton/Pack						
<input type="text" value="1"/>	Case						

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?:

PHARMACY ORDER / BILL UNIT

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

Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?

Is product exempt from DSCSA?

If yes, select exemption:

Other exemption - Write in:

Is product repackaged?

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exception/exemption for product?

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

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	1.7923		3.89	6.69	26.011804	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	24.9122	16.14	12.20	7.48	1473.446	12
Pallet:	1,044.99	47.24	39.37	46.456	86400.671	40

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00382619140026	382619140026
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	12		20382619140020	
<input checked="" type="checkbox"/> Pallet	40			

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

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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?	<input type="checkbox"/> No
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/> No
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/> No
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/> No
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/> No
c. Contact Hazard?	<input type="checkbox"/> No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/> No
e. Does the product contain DEHP?	<input type="checkbox"/> No
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	<input type="text"/>
b. Proper Shipping Name	<input type="text"/>
c. DOT Hazard Class	<input type="text"/>
d. Packing Group	<input type="text"/>
e. Inhalation Hazard?	<input type="checkbox"/> No
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	
a. UN/Identification Number	<input type="text"/>
b. Proper Shipping Name	<input type="text"/>
c. DOT Hazard Class	<input type="text"/>
d. Packing Group	<input type="text"/>
e. Inhalation Hazard?	<input type="checkbox"/> No
Is the product restricted for air shipment? If so, indicate restriction:	
<input type="checkbox"/> Passenger	<input type="checkbox"/> No
<input type="checkbox"/> Cargo	
<input type="checkbox"/> Passenger & Cargo	
Is this a reportable quantity? <input type="checkbox"/> No	
RQ Threshold:	<input type="text"/>
Is this a marine pollutant? <input type="checkbox"/> No	
Is this product shipped utilizing an authorized DOT exception or Special Permit?	
<input type="checkbox"/> No (if yes, identify method below)	
<input type="checkbox"/> Limited Quantity	
<input type="checkbox"/> Consumer Commodity, ORM-D	
<input type="checkbox"/> Small Quantity (49 CFR 173.4)	
<input type="checkbox"/> Special Permit; DOT-SP	
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/>	
ADD'L STORAGE INFORMATION	
Is the Product...	
Controlled Substance?	<input type="checkbox"/> No
Controlled by State(s)?	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No
Schedule No.	<input type="text"/>
Controlled Substance Code	<input type="text"/>
Listed Chemical (List I or II)	<input type="checkbox"/> No
If yes, indicate which:	<input type="text"/>
Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	<input type="checkbox"/> Yes
Restricted to retail pharmacy only:	<input type="text"/>
Restricted to hospital, clinics, and physician offices only:	<input type="text"/>
Restricted from US territories? (explain in comments)	<input type="text"/>
Comments:	<input type="text"/>
SDS Hazard Classification	
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	<input type="checkbox"/> No
NFPA Storage Level:	<input type="text"/>
Is the product a NIOSH hazardous drug? If yes, indicate which:	<input type="checkbox"/> No
	<input type="text"/>
Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>
Waste Characteristics	<input type="text"/>
REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <input type="checkbox"/> No	
If Yes, is it managed with a pharmacy registry?	<input type="text"/>
Website URL:	<input type="text"/>
Med Guide Required	<input type="checkbox"/> No
Limited Distribution Requirement	<input type="checkbox"/> No
Comments / Details: (For example, iPledge program?)	<input type="text"/>
REMS: <input type="checkbox"/> No	
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="text"/>
Wholesale distributor support:	<input type="text"/>
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text" value="IT IS NOT A REMS PRODUCT"/>
Registry: <input type="checkbox"/> No	
Registry Program Contact Name:	<input type="text"/>
Comments	<input type="text" value="IT IS NOT A REMS PRODUCT"/>
Phone:	<input type="text"/>
RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <input type="text"/>	
Is product returnable for credit:	<input type="text"/>
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?	<input type="text"/>
If so, which states? Other requirements? Comments?	<input type="text"/>
MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<input type="text"/>	



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 <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> 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: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>