

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

						Introduction Ty	/pe: New Item		x Final Version			Date:	08-22	2-2024
			PRODUCT INFORMAT	ION					SPECIAL HANI	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	CREEKWOOD P	HARMACEUTICALS	IIC			Applicati	on: ANDA	a Temperatu	re - Indicate the USP tempe	erature range for t	his product			
Application Number for NDA/AN				A2	218673	7.401.000.	7.11.571	a. remperatu	Temperature Range	Controlled Room -		and 25 C (6	3° – 77° F)	
Medical Device Class, if applical			,.									`		
DUNS:	118582565							_	Other Temperature Range I	Requirement				
Proprietary Name (If Applicable) a	and Established N	ame: Metfor	min Hydrochloride Extended	-Release Table	ets, USP 500mg,	500 tablets per bot	tle		(write in)					
Selling Unit NDC:	82619-140-02		Unit of Use NDC:		82619-140-02	UPC:	382619140026		Notes					
UDI	NA		CVX Code:			MVX Code:	NA							
Description:	Metformin Hydrod	chloride Extended-Re	ease Tablets, USP 500mg, 5	500 tablets per	bottle				Is this product to be shipped	d to customers on ic	ce?		No	
	[White to off white	e, oval (Modified Cap	sule) shaped tablet debossed	d with "M16" or	n one side and pl	ain on another side.	Tablets should be free from		Is this product to be shipped	d to customers on d	dry ice?		No	
Active Ingredient(s):		Metformin Hydroch	loride API											
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform					_				Name:		SUJIT SAKP			
Address:	1130 US 46 W				State:	Address 2:	Suite 21 Zip: 07054		Number: Group E-mail:		551-303-933 sujit@cree			
City: Key Contact:	Parsippany Paul Thomas				Email:	-	odpharma.com		Group E-mail:		sujit@cree	kwooupna	irma.com	
Phone Number:	1-732-344-022				Fax:	<u>paur@creekwo</u>	<u>oupilarilla.com</u>	c. Special rec	gulations for product in any	states?			No	
Product Therapeutic Classificatio		Anti-hyperglycemic						o. opeoidi reg	Special returns requirement				No	
Troduct Therapeutic Glassificatio		7 tila Hypergiyeeiille							opecial returns requirement	is for this product:			140	
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only				Protect product (unit of sa	ala) from light?			No	
a legend device?		No	Is the Product	Unit of Use	Offiny		100	e. Shelf life:	Frotect product (unit of Se	ale) Irom light?			24	Months
if yes, enter class #		IVO	Orphan Drug Status	01.11.01.000		Size:	100	C. Onen me.	Initial shelf life at launch (if different):			24	Months
a product kit?		No					500mg							
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	IATION			
component parts						Dosage Form	. Tablets							
reverse numbered?		No				Dosage i oilii	•		Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present				-	_	x Bottle		1 bottel of 50			
latex-free?		Yes	NA			Product Shap	Oval (Modified Capsule) shaped		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes Yes					M/hita ta aff whita	_	Ampule Glass		Minimum or	dor augntit		Yes
opioid?		No				Product Colo	r: White to on-white		Tube		wimimum or	der quantit	y r	res
Cannabinoid?		No	Country of Origin	INDIA			Debossed with "M16" on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		,g			Product Impr	one side on one side and		Vial Liquid Multi		If Yes, how	manv of wh	ich package	type?
hospital scanning?		No	Is this product covered ur	nder the				_				Each		71
If Unit Dose, indicate NDC here:				idei ilie					viai Powder Sqi			Lacii		
ii Crist Dood, iridiodio 142 0 moro.		· ·	Trade Agreements Act (T		No				Vial Powder Sql Vial Power Multi			Inner/Cartor	/Pack	
ii ciii bood, iididato Nbo Horo.		'			No								/Pack	
iii diik 2000, iiididdie 1120 11010.				AA)?	No				Vial Power Multi			Inner/Cartor	/Pack	
The state of the s		·	Trade Agreements Act (T	AA)?					Vial Power Multi Other: Write In		1	Inner/Cartor	ı/Pack	
			Trade Agreements Act (T	AA)?			*If Authorized Generic, other		Vial Power Multi Other: Write In	ARMACY ORDER	1	Inner/Cartor	n/Pack	
I. Orange Book Rating:			Trade Agreements Act (T	AA)?			*If Authorized Generic, other section fields are not applicable	Rec. sell unit	Vial Power Multi Other: Write In PH.	ARMACY ORDER	/ BILL UNIT	Inner/Cartor Case		
	and?:		Trade Agreements Act (T	AA)?				Neo. sen unic	Vial Power Multi Other: Write In PH. to customer? 1 bottle	ARMACY ORDER	1 / BILL UNIT	Inner/Cartor Case nit to pharm Each		
I. Orange Book Rating:	and?:	GLUCOPHAGE® X	Trade Agreements Act (T	DDUCTS	Aut			Rec. sell unit	Vial Power Multi Other: Write In PH. to customer? 1 bottle	ARMACY ORDER	/ BILL UNIT	Inner/Cartor Case nit to pharm Each Gram		
I. Orange Book Rating:	and?:	GLUCOPHAGE® X	Trade Agreements Act (T	DDUCTS	Aut			Neo. sen unic	Vial Power Multi Other: Write In PH. to customer? 1 bottle	ARMACY ORDER	/ BILL UNIT	Inner/Cartor Case nit to pharm Each		
I. Orange Book Rating:		GLUCOPHAGE® X	Trade Agreements Act (T	DDUCTS	Aut			Neo. sen unic	Vial Power Multi Other: Write In PH. to customer? 1 bottle . 1 Vial)	ARMACY ORDER	/ BILL UNIT	Inner/Cartor Case nit to pharm Each Gram Milliliter		
I. Orange Book Rating: II. Generic Equivalent to What Bra		GLUCOPHAGE® X	Trade Agreements Act (T FOR GENERIC DRUG PRO IR 500 mg and 750 mg Y CHAIN SECURITY ACT (E	DDUCTS	Aut			Neo. sen unic	Vial Power Multi Other: Write In PH. to customer? 1 bottle . 1 Vial)]	/ BILL UNIT	Inner/Cartor Case nit to pharm Each Gram Milliliter		
I. Orange Book Rating: II. Generic Equivalent to What Bra		GLUCOPHAGE® X	Trade Agreements Act (T FOR GENERIC DRUG PRO IR 500 mg and 750 mg Y CHAIN SECURITY ACT (E	DDUCTS	Aut			Neo. sen unic	Vial Power Multi Other: Write In PH. to customer? 1 bottle .1 Vial)	AND PACKING IN	/ BILL UNIT	Inner/Cartor Case nit to pharm Each Gram Milliliter		Saleable #
I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?		GLUCOPHAGE® X	Trade Agreements Act (T FOR GENERIC DRUG PRO IR 500 mg and 750 mg Y CHAIN SECURITY ACT (D Yes	DDUCTS	Auti RMATION GLN:	850045940003		Neo. sen unic	Vial Power Multi Other: Write In PH. to customer? 1 bottle . 1 Vial)	AND PACKING IN	/ BILL UNIT Rx billing un X	Inner/Cartor Case nit to pharm Each Gram Milliliter	acy:	Saleable #
I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	ition of manufactu	GLUCOPHAGE® X DRUG SUPPL	Trade Agreements Act (T FOR GENERIC DRUG PRO IR 500 mg and 750 mg Y CHAIN SECURITY ACT (E Yes	DDUCTS	Aut RMATION GLN: GCP: If yes, was ori	850045940003 850045940		Neo. sen unic	Vial Power Multi Other: Write In PH. to customer? 1 bottle 1 Vial) ITEM Weight Lbs.	AND PACKING IN	/ BILL UNIT Rx billing ut X IFORMATION ons (US msm Width	Inner/Cartor Case nit to pharm Each Gram Milliliter nts.) Height	Volume (Cube)	Pieces
I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	ition of manufactu	GLUCOPHAGE® X DRUG SUPPL urer?	Trade Agreements Act (T FOR GENERIC DRUG PRO IR 500 mg and 750 mg Y CHAIN SECURITY ACT (E Yes	DDUCTS	Aut RMATION GLN: GCP: If yes, was ori purchased dir	850045940003 850045940 ginal product ect from mfr?	section fields are not applicable	(Write-in, e.g	Vial Power Multi Other: Write In PH. to customer? 1 bottle 1 Vial) ITEM Weight Lbs. 1.7923	AND PACKING IN	/ BILL UNIT Rx billing us X IFORMATION Ons (US msm	Inner/Cartor Case nit to pharm Each Gram Milliliter	acy: Volume	
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I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA definition is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	ition of manufactu s exclusive distrib on/exemption for p m FDA.	GLUCOPHAGE® > DRUG SUPPL urer? urtor? product?	Trade Agreements Act (T FOR GENERIC DRUG PRO IR 500 mg and 750 mg Y CHAIN SECURITY ACT (E Yes No No No	DDUCTS DDUCTS DDSCSA) INFO	Aut RMATION GLN: GCP: If yes, was ori purchased dir	850045940003 850045940 ginal product ect from mfr? he manufacturer fo	section fields are not applicable	(Write-in, e.g	Vial Power Multi Other: Write In PH to customer? 1 bottle .1 Vial) ITEM Weight Lbs. 1.7923 Bundle/	AND PACKING IN Dimensio	/ BILL UNIT Rx billing un X IFORMATION Ons (US msm Width 3.89	Inner/Cartor Case nit to pharm Each Gram Milliliter hts.) Height 6.69	Volume (Cube) 26.011804	Pieces
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 For Designated Drop Ship Only Products, Please Use Page 3

MATE	RIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	No	SDS Hazard Classification	
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	Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard	
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	
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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	
c. DOT Hazard Class d. Packing Group		Hazardous Waste Identification	
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. Packing Group e. Inhalation Hazard?	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	
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:	DEA #: NCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments IT IS NOT A REMS PRODUCT	
SP# ADD'L STORAGE INFORMATION		Registry: No Registry Program Contact Name: Comments IT IS NOT A REMS PRODUCT	Phone:
Is the Product			
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	No No	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-
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	Policy.pdf	
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:			
MISC	ELLANEO	US NOTES and/or Image of Product Barcode:	

Release DATE: 02/13/2024



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 f	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:
b. Autofax	Fax Number:	
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only	Phone No.:	
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:		Ships for second day receipt:
Supplier's Customer Service Number:	Direct content of platform (D. 9. C)	Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #:	Name: Direct customer solutions (R & S)	
	Phone: 1-800-655-7556	
Expedited Freight Cha	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order	er:	Overnight receipt available:
Drop Ship service fee billed with each order	r:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:		Days of week overnight is available:
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Clas	ss of Trade Restriction:	PO Receipt Cut off time:
	harmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time:
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician	a offices only:	Phone: Phone #:
Restricted from US territories? (explain in co		Order receipt method: Fax: Fax #:
Comments:	oninonia)	EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Info	formation Required to Process PO:	Return Instructions
	ormanion required to Frocess Fe.	
Patient Procedure Date:		Contact # if product is received damaged: Is product returnable for credit:
Physician Name: Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		OND Link to returns policy.
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?