

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

						Introduction T	/pe: New Item		x Final Version			Date:	08-22	2-2024
			PRODUCT INFORMAT	ION					SPECIAL HAND	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	CREEKWOOD P	HARMACEUTICALS	II C			Applicat	on: ANDA	a Temperatu	re - Indicate the USP tempe	rature range for t	his product			
Application Number for NDA/AN				A2	218673	7 (5)	7.11.571	a. remperatu		Controlled Room -		and 25 C (6	8° – 77° F)	
Medical Device Class, if applical									·g-					
DUNS:	118582565							_	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established N	ame: Metfor	min Hydrochloride Extended-	Release Table	ets, USP 500mg,	100 tablets per bo	tle		(write in)	•				
Selling Unit NDC:	82619-140-01		Unit of Use NDC:		82619-140-01	UPC:	382619140019		Notes					
UDI	NA		CVX Code:			MVX Code:	NA							
Description:	Metformin Hydro	chloride Extended-Rel	ease Tablets, USP 500mg, 1	00 tablets per	bottle				Is this product to be shipped	to customers on ic	ce?		No	1
	[White to off white	e, oval (Modified Caps	sule) shaped tablet debossed	with "M16" or	n one side and pl	ain on another side	Tablets should be free from		Is this product to be shipped	to customers on d	Iry ice?		No	
Active Ingredient(s):		Metformin Hydroch	oride API											
								b. Contact fo	r temperature excursion que	estions:				
URL for Additional Product Inform					1				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:		<u>sujit@cree</u>	kwooupna	arma.com	
Phone Number:	1-732-344-022				Fax:	paul@creekwc	<u>oupilarilla.com</u>	c. Special rec	gulations for product in any	states?			No	1
Product Therapeutic Classificatio		Anti-hyperglycemic			- Luxi			o. opeciai reg	Special returns requirement				No	-
Troduct Therapeutic Glassificatio	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	7 tha hypergrycenno							opecial returns requirement	s for this product:			140	
	ADDITI	ONAL PRODUCT INI	FORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship	Only				Protect product (unit of sa	ola) from light?			No	1
a legend device?		No	Is the Product	Unit of Use	Offiny		100	e. Shelf life:	Frotect product (unit of Sa	ile) iroin light?			24	Months
if yes, enter class #		140	Orphan Drug Status	01111 01 000		Size:	100	III c. onen me.	Initial shelf life at launch (if different):			24	Months
a product kit?		No				Ot	500mg							
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts						Dosage Forn	. Tablets							
reverse numbered?		No				Dosage i oili	•]	Unit of Sale		What is the		g unit?	
co-licensed?		No	Allergens Present				-	- 1	x Bottle		1 bottel of 10			
latex-free?		Yes	NA			Product Sha	Oval (Modified Capsule) shaped		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes					M/hito to off white	-	Ampule Glass		Minimum or	dor augntit	w2	Yes
opioid?		No No				Product Cold	r: White to on-white		Tube		wiinimum 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 Imp	int: 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 un	nder the				_	Vial Powder Sql			Each		,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (T.	ΛΛ\2	No				Vial Power Multi			Inner/Cartor	/Pack	
			Trade Agreements Act (1)	^^):	110				viair orror main			iiiiiei/Cartoi	// ack	
			Trade Agreements Act (1)	AA):	140				Other: Write In			Case	// dck	
			FOR GENERIC DRUG PRO		140								VI don	
									Other: Write In		1		VI ack	
						horized Generic	*If Authorized Generic, other		Other: Write In	ARMACY ORDER	1		VI dek	
I. Orange Book Rating:			FOR GENERIC DRUG PRO			horized Generic	*If Authorized Generic, other section fields are not applicable	Rec. sell unit	Other: Write In PH/	ARMACY ORDER	/ BILL UNIT	Case		
I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	GLUCOPHAGE® X				horized Generic		Tree. Sen unit	Other: Write In PH/ to customer? 1 bottle	ARMACY ORDER	1 / BILL UNIT	Case nit to pharm Each		
	and?:		FOR GENERIC DRUG PRO	DUCTS	x Aut	horized Generic		Rec. sell unit	Other: Write In PH/ to customer? 1 bottle	ARMACY ORDER	/ BILL UNIT	Case nit to pharm Each Gram		
	and?:		FOR GENERIC DRUG PRO	DUCTS	x Aut	horized Generic		Tree. Sen unit	Other: Write In PH/ to customer? 1 bottle	ARMACY ORDER	/ BILL UNIT	Case nit to pharm Each		
II. Generic Equivalent to What Bra		DRUG SUPPL	FOR GENERIC DRUG PRO	DUCTS	x Aut	horized Generic		Tree. Sen unit	Other: Write In PH/ to customer? 1 bottle . 1 Vial)	ARMACY ORDER	/ BILL UNIT Rx billing u	nit to pharm Each Gram Milliliter		
		DRUG SUPPL	FOR GENERIC DRUG PRO R 500 mg and 750 mg CHAIN SECURITY ACT (D	DUCTS	x Aut			Tree. Sen unit	Other: Write In PH/ to customer? 1 bottle . 1 Vial)		/ BILL UNIT Rx billing u	nit to pharm Each Gram Milliliter		
II. Generic Equivalent to What Bra		DRUG SUPPL	FOR GENERIC DRUG PRO R 500 mg and 750 mg CHAIN SECURITY ACT (D	DUCTS	x Aut			Tree. Sen unit	Other: Write In PH/ to customer? 1 bottle . 1 Vial)	AND PACKING IN	/ BILL UNIT Rx billing ui	nit to pharm Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?		DRUG SUPPL	FOR GENERIC DRUG PRO R 500 mg and 750 mg Y CHAIN SECURITY ACT (D	DUCTS	x Auti	850045940003		Tree. Sen unit	Other: Write In PH/ to customer? 1 bottle . 1 Vial)	AND PACKING IN	7 BILL UNIT Rx billing us X	nit to pharm Each Gram Milliliter	nacy:	Saleable #
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	DRUG SUPPL	FOR GENERIC DRUG PRO R 500 mg and 750 mg Y CHAIN SECURITY ACT (D Yes	DUCTS	x Auti	850045940003 850045940 Iginal product		Tree. Sen unit	Other: Write In PH/ to customer? 1 bottle .1 Vial) ITEM Weight Lbs.	AND PACKING IN	/ BILL UNIT Rx billing un X IFORMATION Ons (US msm Width	Case nit to pharm Each Gram Milliliter nts.) Height	Volume (Cube)	Pieces
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	DRUG SUPPL	FOR GENERIC DRUG PRO R 500 mg and 750 mg / CHAIN SECURITY ACT (D Yes No	DUCTS	x Auti 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	Other: Write In PH/ to customer? 1 bottle .1 Vial) ITEM Weight Lbs. 0.2998	AND PACKING IN	7 BILL UNIT Rx billing us X IFORMATION ons (US msm	nit to pharm Each Gram Milliliter	nacy:	
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 Has FDA granted waiver/exceptio	ition of manufactors s exclusive distrib	DRUG SUPPL	FOR GENERIC DRUG PRO R 500 mg and 750 mg Y CHAIN SECURITY ACT (D Yes	DUCTS	x Auti RMATION GLN: GCP: If yes, was ori purchased dir	850045940003 850045940 ginal product ect from mfr?		(Write-in, e.g	Other: Write In PH/ to customer? 1 bottle .1 Vial) ITEM Weight Lbs. 0.2998	AND PACKING IN	/ BILL UNIT Rx billing un X IFORMATION Ons (US msm Width	Case nit to pharm Each Gram Milliliter nts.) Height	Volume (Cube)	Pieces
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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 Has FDA granted waiver/exceptio	ition of manufactu s exclusive distrib on/exemption for p m FDA.	DRUG SUPPL' urer? urer? utor? product?	FOR GENERIC DRUG PRO R 500 mg and 750 mg / CHAIN SECURITY ACT (D Yes No No No	DUCTS DSCSA) INFOR	x Auti RMATION GLN: GCP: If yes, was ori purchased dir	850045940003 850045940 ginal product rect from mfr? re manufacturer for	section fields are not applicable	(Write-in, e.g	Other: Write In PH/ to customer? 1 bottle .1 Vial) ITEM Weight Lbs. 0.2998 Bundle/	AND PACKING IN Dimensio	/ BILL UNIT Rx billing us X IFORMATION ons (US msm Width 2.63	Case hit to pharm Each Gram Milliliter tts.) Height 4.13	Volume (Cube)	Pieces 1
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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 Has FDA granted waiver/exceptio If yes, attach documentation fro	ition of manufactu s exclusive distrib on/exemption for p m FDA.	DRUG SUPPL urer? uttor? grin Galeable Quantity	FOR GENERIC DRUG PRO R 500 mg and 750 mg Y CHAIN SECURITY ACT (D Yes No No No No	DUCTS DSCSA) INFOR	RMATION GLN: GCP: If yes, was ori purchased dir Provide source GTIM 0038	850045940003 850045940 ginal product rect from mfr? re manufacturer for	r repackaged product Unit of Use GTIN-14	(Write-in, e.g	Other: Write In PH/ to customer? 1 bottle .1 Vial) ITEM Weight Lbs. 0.2998 Bundle/ 7.1991	AND PACKING IN Dimension Depth 11.22	/ BILL UNIT Rx billing un X IFORMATION ons (US msm Width 2.63 8.06 39.37	Case Init to pharm Each Gram Milliliter Its.) Height 4.13	Volume (Cube) 10.84125	1 24 60
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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:	U	ts Ships for second day receipt:
Supplier's Customer Service Number:	Disease southern a solution of (D. 9. C)	Ships regular ground for 3-10 days receipt:
. ,	Name: Direct customer solutions (R & S)	
	Phone: 1-800-655-7556	
Expedited Freight Char	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order	r:	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: Monday
Comments:	·	Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Clas	ss of Trade Restriction:	PO Receipt Cut off time:
	narmacy, 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	offices only	Phone: Phone #:
Restricted from US territories? (explain in co		Order receipt method: Fax: Fax #:
Comments:	oninone)	EDI:
Genimente.		Overnight Fees apply:
		Other fees apply:
Other Data Info	ormation Required to Process PO:	Return Instructions
	omanon roquirou to 1 resesse 1 e.	
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:	
	missemanissas (Notes).	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?