

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

Version 2021						Introduction Typ	e: New Item		Final Version			Date:	09-18	
			PRODUCT INFORMAT	TION					SPECIAL HAND	LING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	CREEKWOOD P	HARMACEUTICALS I	LC			Application	n: ANDA	a. Temperature	- Indicate the USP tempe	rature range for the	his product.			
Application Number for NDA/AN				A2	217732					Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical		vo ro(n)(mod dorne							omporature range				,	
DUNS:	118582565				1			-	Other Temperature Range R	Pequirement				
Proprietary Name (If Applicable) a		ame: Fenofih	rate Tablets, USP 120 mg					`	(write in)	(cquirement				
Selling Unit NDC:	82619-102-01	unio: r onone	Unit of Use NDC:		82619-102-01	UPC: 3	82619102017		Notes					
UDI	NA		CVX Code:		,	MVX Code: N								
			4								_			
Description:	Fenofibrate Table	its, USP 120 mg are v	white to off-white, oval shap	oed, uncoated to	ablets debossed	with "294" on one sid	e and plain on other side.		s this product to be shipped				No	
Anthon In mondle of (a)		Fenofibrate USP						-   '	s this product to be shipped	to customers on d	iry ice?		No	
Active Ingredient(s):		renolibrate USP						h Contact for t	emperature excursion que	etione				
URL for Additional Product Inform	mation:							_	Vame:		SUJIT SAKP	٨١		
Address:	1130 US 46 W				1	Address 2: S	uite 21	_	Number:		551-303-933			
City:	Parsippany				State:		Zip: 07054		Group E-mail:		sujit@cree		rma com	
Key Contact:	Paul Thomas				Email:	paul@creekwoo			Sroup L-man.		<u>sujit@cree</u>	KWOOUDIIG	iiiia.com	
Phone Number:	601-259-4116				Fax:	paditwereekwoo	арпатна.сот	c. Special regul	ations for product in any	states?			No	
Product Therapeutic Classification		Primary hypercholes	sterolemia, Hypertriglycerid	lemia	-				Special returns requirements				No	
Froduct Therapeutic Classification	л.	1 Tilliary Trypercholes	sterolernia, r typertrigiycena	emia				`	special returns requirement	s for this product?			INU	
	_ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DE	SCRIPTION INFORMATION	d Store produc	t (unit of sale) upright?				No	
	ADDITIO	JUNE I RODUCT INF		D:		- I NODUCT DE	JOHN HON INFORMATION	<b>-1</b>						
The product is?			Is the Product	Direct-Ship	Only				Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	17.75 x 7.65 mm	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						nitial shelf life at launch (i	f different):			24	Months
a product kit?		No				Strength:	120 mg			ODDED INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				T-1-1-4			ORDER INFORM	ATION			
component parts reverse numbered?		NI-				Dosage Form:	Tablet		Jnit of Sale		What is the	NDC colling	unit?	
co-licensed?		No No	Allergens Present					III - i	x Bottle		1 bottle of 90		, unit:	
latex-free?		Yes	Allergens Fresent				Oval shaped	-	Box/Carton		(Write-in, e.		O Viole)	
preservative-free?		Yes	Presence of Lactose, da	iry Product		Product Shape	: Oval shapeu	-	Ampule		(**************************************	g. 1 DOX 01 1	o viais)	
correctional institution block?		No					White to off-white		Glass		Minimum or	der auantit	12	Yes
opioid?		No				Product Color:	William to on William		Tube		······································	uci quantit	,.	103
Cannabinoid?		No	Country of Origin	INDIA			294		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for	110	,g			Product Imprin	t				If Van haw	nany of wh	iah maaliama	
									Vial Liquid Multi					type?
	ariit dooo roi	No	Is this product covered u	under the					Vial Liquid Multi Vial Powder Sql				ісп раскаде	type?
hospital scanning?	ariii 4000 roi	No	Is this product covered u		No				Vial Powder Sql		12	Each		type?
	a.m. 4656 161	No			No						12			type?
hospital scanning?			Trade Agreements Act (	TAA)?	No				Vial Powder Sql Vial Power Multi		12	Each Inner/Carton		type?
hospital scanning?				TAA)?	No				Vial Powder Sql Vial Power Multi		12	Each Inner/Carton		type?
hospital scanning?			Trade Agreements Act (	TAA)?			f Authorized Generic, other		Vial Powder Sql Vial Power Multi Other: Write In	ARMACY ORDER A	12	Each Inner/Carton		type?
hospital scanning? If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?		thorized Generic *I		Rec. sell unit to	Vial Powder Sql Vial Power Multi Other: Write In	ARMACY ORDER	12 1	Each Inner/Carton Case	l/Pack	type?
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hospital scanning? If Unit Dose, indicate NDC here:	AB		Trade Agreements Act (	TAA)?		thorized Generic *I	f Authorized Generic, other	1 bot	Vial Powder Sql Vial Power Multi Other: Write In  PHA customer? tle of 90 tablets	ARMACY ORDER A	12 1 / BILL UNIT Rx billing ur	Each Inner/Carton Case	l/Pack	type?
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hospital scanning? If Unit Dose, indicate NDC here:  I. Orange Book Rating: II. Generic Equivalent to What Bra	AB and?:	FENOGLIDE DRUG SUPPLY	Trade Agreements Act (	ODUCTS	Au	thorized Generic *I	f Authorized Generic, other	1 bot	Vial Powder Sql Vial Power Multi Other: Write In  PHA  customer? tle of 90 tablets Vial)	ARMACY ORDER /	12 1   SILL UNIT   Rx billing ur	Each Inner/Cartor Case  sit to pharm Each Gram	l/Pack	type?
hospital scanning? If Unit Dose, indicate NDC here:  I. Orange Book Rating: II. Generic Equivalent to What Bra	AB and?:	FENOGLIDE DRUG SUPPLY	Trade Agreements Act ( FOR GENERIC DRUG PRO CHAIN SECURITY ACT (	ODUCTS	Au	thorized Generic *1 st	f Authorized Generic, other	1 bot	Vial Powder Sql Vial Power Multi Other: Write In  PHA  customer? tle of 90 tablets Vial)		12 1   SILL UNIT   Rx billing ur	Each Inner/Cartor Case  sit to pharm Each Gram	l/Pack	type?
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In Unit Dose, indicate NDC here:  I. Orange Book Rating: II. Generic Equivalent to What Brack Br	AB and?: ition of manufactu s exclusive distrib infexemption for p om FDA.	PENOGLIDE  DRUG SUPPLY  irer?  GTIN  Saleable Quantity  1  12	Trade Agreements Act ( FOR GENERIC DRUG PRO CHAIN SECURITY ACT ( Yes  NO NO NO NO AND HIBCC PRODUCT IN	DSCSA) INFO	Au  RMATION  GLN:  GCP:  If yes, was on purchased di  Provide sour	thorized Generic '1 st	f Authorized Generic, other action fields are not applicable repackaged product  Unit of Use GTIN-14	ttem/Each: Box/Carton/Bui Inner Pack: Case: Pallet:	Vial Powder Sql Vial Power Multi Other: Write In  PHA Customer? tile of 90 tablets Vial)  ITEM  Weight Lbs.  0.2  dulle/ 2.89 829  COST INFORMATION	AND PACKING IN  Dimensic Depth  1.92  8.00  48	ISOMATION  IFORMATION  Ons (US msm Width  1.92  6.20  40  Vendor #: Whsl. Code	Each Inner/Cartor Case  Sit to pharm Each Gram Milliliter  ts.) Height 4.40  20  //HOLESAL	Volume (Cube) 16.22 248.00 38400.00	Saleable # Pieces  1  12  3408
In Unit Dose, indicate NDC here:  I. Orange Book Rating: II. Generic Equivalent to What Brack Br	AB and?: ition of manufactu s exclusive distrib infexemption for p om FDA.	PENOGLIDE  DRUG SUPPLY  irer?  GTIN  Saleable Quantity  1  12	Trade Agreements Act ( FOR GENERIC DRUG PRO CHAIN SECURITY ACT ( Yes  NO NO NO NO AND HIBCC PRODUCT IN	DSCSA) INFO	Au  RMATION  GLN:  GCP:  If yes, was on purchased di  Provide sour	thorized Generic '1 st	f Authorized Generic, other action fields are not applicable repackaged product  Unit of Use GTIN-14	I bot (Write-in, e.g. 1  Item/Each: Box/Carton/Bui Inner Pack: Case: Pallet:  Regular Cost Invoice Cost (M	Vial Powder Sql Vial Power Multi Other: Write In  PHA Customer? tile of 90 tablets Vial)  ITEM  Weight Lbs.  0.2  dulle/ 2.89 829  COST INFORMATION	AND PACKING IN  Dimensic Depth  1.92  8.00  48	ISOMATION  IFORMATION  Ons (US msm Width  1.92  6.20  40  Vendor #: Whsl. Code	Each Inner/Cartor Case  Sit to pharm Each Gram Milliliter  ts.) Height 4.40  20  //HOLESAL	Volume (Cube) 16.22 248.00 38400.00	Saleable # Pieces  1  12  3408
Is product exemption: Other exemption by manufacturer's Has FDA granted waiver/exception If yes, attach documentation fro	AB and?: ition of manufactu s exclusive distrib infexemption for p om FDA.	FENOGLIDE  DRUG SUPPLY  irer?  GTIN  Saleable Quantity  1  12  3408	Trade Agreements Act ( FOR GENERIC DRUG PRO CHAIN SECURITY ACT ( Yes  NO NO NO NO HIBCC PRODUCT IN	DSCSA) INFORMATION	Au  RMATION  GLN:  GCP:  If yes, was oi purchased di Provide sour  GTI  003  203	850045940003  850045940  850045940  iginal product rect from mfr? cce manufacturer for 182619102017  82619102011	f Authorized Generic, other action fields are not applicable repackaged product  Unit of Use GTIN-14	Item/Each: Box/Carton/But Inner Pack: Case: Pallet:  Regular Cost Invoice Cost (W. As of date:	Vial Powder Sql Vial Power Multi Other: Write In  PHA Customer? tile of 90 tablets Vial)  ITEM  Weight Lbs.  0.2  0.2  COST INFORMATION  VAC) (\$)	AND PACKING IN  Dimensic Depth  1.92  8.00  48	ISOMATION  IFORMATION  Ons (US msm Width  1.92  6.20  40  Vendor #: Whsl. Code	Each Inner/Cartor Case  Sit to pharm Each Gram Milliliter  ts.) Height 4.40  20  //HOLESAL	Volume (Cube) 16.22 248.00 38400.00	Saleable # Pieces  1  12  3408



Version 2021

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

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

Release DATE: 16/09/2023



# **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	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:	Units	Ships for second day receipt:					
Supplier's Customer Service Number: Contracted 3PL company / contact #:	Name: Direct customer solutions (R & S)	Ships regular ground for 3-10 days receipt:					
Contracted SFE company / contact #.	Phone: 1-800-655-7556						
Franchited Freight Che		Overwight and Driegity Overwight DO Pressesing					
	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:					
Cla	ss of Trade Restriction:	PO Receipt Cut off time:					
No restriction: Select YES if sold to retail ph	narmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:					
Restricted to retail pharmacy only:		PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician	offices only:	Order receipt method: Phone: Phone #:					
Restricted from US territories? (explain in co	omments)	Fax: Fax #:					
Comments:		EDI:					
		Overnight Fees apply:					
		Other fees apply:					
Other Data Inf	ormation Required to Process PO:	Return Instructions					
Patient Procedure Date:		Contact # if product is received damaged:					
Physician Name:		Is product returnable for credit:					
Physician/Clinic Phone # Physician State License #		URL/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					
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure?					
		Is product order for restocking purposes?					