

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

Version 2021						Introduction	Type:	Post Launch Change		x Final Version			Date:	10/22	2/2025
			PRODUCT INFORMA	TION						SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Applica	ation:	ANDA	a. Temperatu	re - Indicate the USP tempe	rature range for t	nis product.			
Application Number for NDA/AN	NDA/BLA (drug); Pl	//A/510(k)(med devic	e):	214	603				1	Temperature Range	Controlled Room -	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applica	able:								Ì						
DUNS:	11-856-3719									Other Temperature Range R	equirement				
Proprietary Name (If Applicable)	and Established Na	me: Gemfib	prozil Tablets, USP 600 mg						Ī	(write in)					
Selling Unit NDC:	31722-128-60		Unit of Use NDC:		31722-128-60	UPC:	33172212	28605		Notes					
UDI			CVX Code:			MVX Code:									
Description:	Gemfibrozil Table	ts. USP 600 ma							ř I	Is this product to be shipped	to customers on ic	ce?		No	
		,								Is this product to be shipped				No	
Active Ingredient(s):		Gemfibrozil, USP							Ì						
									b. Contact fo	r temperature excursion que	stions:				
URL for Additional Product Inforr		www.camberpharma	a.com							Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:				Number:		732-529-042			
City:	Piscataway				State:	NJ	Zip: (Group E-mail:		somaraju@h	eterousa.com	<u>1</u>	
Key Contact:	Customer Service 1-866-827-3647				Email: Fax:	customerservice(@camberpl	harma.com						No	1
Phone Number:		Lipid regulating age	4		гах.	132-302-0100			c. Special reg	gulations for product in any					1
Product Therapeutic Classification	on:	Lipid regulating age	TIL .							Special returns requirements	for this product?			No	1
	ADDITI	ONAL PRODUCT INF	OPMATION			DRODUCT	DESCRIPT	TION INFORMATION	d 64aua muad	uct (unit of sale) upright?				No	1
	ADDITI	ONAL PRODUCT INF				PRODUCT	DESCRIPT	TION INFORMATION	a. Store prod	· · · · ·					1
The product is?			Is the Product	Direct-Ship Or	nly					Protect product (unit of sal	e) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	60) ct	e. Shelf life:					24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				60	00 mg		Initial shelf life at launch (if	different):				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:	00	oo mg			ORDER INFORM	IATION			
component parts			1 DA Approvar otatas				Fil	Im coated tablet			011.D_11.11.011.11				
reverse numbered?		No				Dosage Form	m:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 6			
latex-free?		Yes	Corn Alor	hol, Animal		Product Sha	O\	val		Box/Carton		(Write-in, e.	g. 1 Box of 10	Vials)	
preservative-free?		Yes	Corn, Aice	nioi, Ammai		Froduct Sila				Ampule					
correctional institution block?		No				Product Col	lor: W	hite to off white		Glass		Minimum or	der quantity	?	Yes
opioid?		No								Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imp	orint: Del	bossed with '1' with two partial ects on one side and two partial		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		In Abita was done a conservation					ects on other side		Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered under the Agreements Act (*)		Vee					Vial Powder Sgl Vial Powder Multi			Each Inner/Carton	/Daals	
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)!	Yes					Other: Write In			Case	Pack	
			FOR GENERIC DRUG PR	ODUCTS						Other, write in			Case		
			FOR GENERIC DRUG PR	000013											
					Δuth	norized Generic	*If Author	rized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I Common Book Books	AD				7100	ionzed Generio		elds are not applicable	Boo coll unit	to customer?			. 14. 4 la		
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB	Lopid							Rec. sell unit	to customer?		Rx billing u		icy:	
ii. Generic Equivalent to what Bra	anu?:	Lopiu							(Write-in, e.g	1 Vial)			Each Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION				(Willo-III, C.g	. I viaij			Milliliter		
				, , , , , , , , , , , , , , , , , , , ,											
Does supplier meet DSCSA defin	nition of manufactur	er?	Yes	T	GLN:	0331722498975				ITEM	AND PACKING I	NFORMATION			
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:						Dimensi	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:									' [Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was orig	ginal product pur	rchased		Item/Each:	0.17	1.83	1.83	3.4	11.39	1
Is product sold by manufacturer's			Yes		direct from mf	r?					1.03	1.03	5.4	11.39	
Has FDA granted waiver/exception		oduct?	No		Provide source	e manufacturer fo	or repacka	ged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro	om FDA.								Inner Pack:						
		0.50	U AND LUDGO DEGELIGE	UEODALA ELON					Case:	4.45	12	8.5	4	408	24
		GIII	N AND HIBCC PRODUCT I	NFORMATION					D-II-4						
		aleable Quantity	HIBCC		GTIN	1.14		Unit of Use GTIN-14	Pallet:						
Saleable Unit of Measure		aleable Quantity	HIDCC			1-14 1722128605		Unit of Use G1IN-14 00331722128605							
Saleable Unit of Measure	8	1			0033	1722120003		00331722120003		COST INFORMATION		,	NHOLESALE	R USE ONL	γ.
X Item/Each	S	1					_								
X Item/Each Box/Carton/Bundle/Inner Pack	5	24			1033	1722128602									
X Item/Each	•	24			1033	1722128602	-		Regular Cost	:		Vendor #:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case		24			1033	1722128602			Regular Cost		\$10.42		#:		
X Item/Each Box/Carton/Bundle/Inner Pack X Case		24			1033	1722128602				(WAC) (\$)	\$10.42	Vendor #: Whsl. Code Fineline Co			
X Item/Each Box/Carton/Bundle/Inner Pack X Case		24			1033	1722128602					\$10.42	Whsl. Code			
X Item/Each Box/Carton/Bundle/Inner Pack X Case		24			1033	1722128602			Invoice Cost	(WAC) (\$)	\$10.42	Whsl. Code			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	S								Invoice Cost As of date:	(WAC) (\$) 3/4/2021	\$10.42	Whsl. Code			
X Item/Each Box/Carton/Bundle/Inner Pack X Case			Attach copy of SAFETY D/	NTA SHEET (SDS		d letter, PACKAGE		LABEL AND PHOTO OF F	Invoice Cost As of date:	(WAC) (\$) 3/4/2021	\$10.42	Whsl. Code			



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For Designated Drop Ship Only Products, Please Use Page 3

MATERI.	AL HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	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?	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	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	Is the product a NIOSH hazardous drug? If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard? Is this product regulated for shipment by IATA?	EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS					
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	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	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: No Phone: Phone: DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP# ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments No Phone:					
Is the Product	Comments					
Controlled Substance? Controlled by State(s)? ARCOS Reportable? No Controlled Substance Code Listed Chemical (List I or II) If yes, indicate which:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: Yes					
	URL/Link to returns policy: 'es contact - customerservice@camberpharma.com					
	- J					
Restricted to hospital, clinics, and physician offices only:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?					
Comments:	No If so, which states? Other requirements? Comments?					
MISGEL	LANEOUS NOTES and/or Image of Product Barcode:					



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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		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #:	Fax Number: Fax Number: Phone No.: Site Address:	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:
	Phone:	
Expedited Freight Cha	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each orde	er:	Overnight receipt available:
Drop Ship service fee billed with each orde	er:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Cla	ass of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail p Restricted to retail pharmacy only: Restricted to hospital, clinics, and physicia Restricted from US territories? (explain in of Comments:		Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data In	formation Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	Miscellaneous Notes:	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?
	misochaneous notes.	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?