

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

Version 2024						Introduction Type	e: New Item	x	Final Version			Date:	12/19	/2024
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application	ı: ANDA	a. Temperature - Ind	licate the USP temp	erature range for th	nis product.			
Application Number for NDA/AN	DA/BLA; PMA/510	O(k): 210500				NDA 505(b) Type:	NOT APPLICABLE	Tempe	erature Range	Controlled Room -	between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applical														
DUNS:	11-856-3719								Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Dimethy	yl Fumarate Delayed-Releas	se Capsules 24					(write in)					
Selling Unit NDC: UDI	31722-658-32		Unit of Use NDC: CVX Code:		31722-658-32	UPC: 33	31722658324	Notes						
			1			WVX Code.		1						
Description:	Dimethyl Fumara	te Delayed-Release Ca	apsules 240 mg						product to be shippe				No No	
Active Ingredient(s): Dimethyl fumarate									product to be shippe	a to customers on a	ry ice?		INO	
								b. Contact for tempe		estions:				
URL for Additional Product Inform		www.camberpharma.	.com			Address 2:		Name			Soma Raju			
Address:	800 Centennial A Piscataway	ive, Suite 1			State:		in. 08854	Numb			732-529-042		^	
City: Key Contact:	Customer Service	e	State:         NJ         Zip:         08854           Email:         customerservice@camberpharma.com					Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulation	s for product in any	states?			No	
Product Therapeutic Classificatio	n:	Fumaric acid derivat	ive (NRF2 activator)		1				al returns requiremen				No	
Special (state equation and equ														
	ADDIT	IONAL PRODUCT INF	ORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store product (un	it of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	nly				ct product (unit of sa	ale) 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 #		la.	Orphan Drug Status				0.10	Initial	shelf life at launch (	if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	240 mg			ORDER INFORM	ATION			
component parts			1 DA Approvar Glatas				Hard gelatin, delayed-							
reverse numbered?		No				Dosage Form:	release capsule	Unit o	f Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					x			1 Bottle of 60			
latex-free?		Yes	Dye, Corn, Alcohol, Ar		s, Sugar,	Product Shape:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 10	) Vials)	
preservative-free? correctional institution block?		Yes No	Oats,	Speit			White opaque cap and		Ampule Glass		Minimum or	dor augntitu	•	Yes
opioid?		No				Product Color:	white opaque body		Tube		William Or	uer quantity	ſ	165
Cannabinoid?		No	Country of Origin	India		Beer desert less select	Imprinted with 'H' on can		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		, ,			Product Imprint	and 'D15' on body		Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?
hospital scanning?			Is this product covered ur						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No				Vial Powder Multi Other: Write In			Inner/Carton	/Pack	
			FOR GENERIC DRUG PRO	DUCTS					Other. Write III			Case		
			TOR GENERIC DROG FRO	300013										
					Au	uthorized Generic *If	Authorized Generic, other		Pł	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					se	ection fields are not applicable	Rec. sell unit to cust	tomer?		Rx billing ur	nit to pharma	асу:	
II. Generic Equivalent to What Bra	nd?:	Tecfidera										Each		
		DRIIC CURRI	Y CHAIN SECURITY ACT (I	Dece A) INFO	MATION			(Write-in, e.g. 1 Vial)				Gram		
		DRUG SUPPL	CHAIN SECURITY ACT (I	JSCSA) INFOR	IWATION			HCPCS J-Code:				Milliliter		
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes	Т	GLN:	0331722498975			ITEN	AND PACKING IN	IFORMATION	I		
Is product exempt from DSCSA?		·	No											
If yes, select exemption:					GCP:			1	Martine I I in	Dimension	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		riginal product purcha	sed	Item/Each:	0.15	2	2	4.1	16.40	1
Is product sold by manufacturer's			Yes No	-	direct from m		mankanad mandust	Box/Carton/Bundle/						
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	INO		Provide sour	ce manufacturer for re	ераскадей ргодист	Inner Pack:						
. , ,								Case:	0.05	10.05	0.5	0.75	4007.00	48
		GTIN	I AND HIBCC PRODUCT IN	IFORMATION					8.65	13.25	9.5	9.75	1227.28	48
Onlands Half of Manager	DEID : 0/40							Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC		GTI	IN-14	Unit of Use GTIN-14							
x Item/Each	N	Quantity 1			003	331722658324	00331722658324							
Box/Carton/Bundle/Inner Pack								CC	OST INFORMATION		\	WHOLESALI	ER USE ONL	Y:
X Case	N	48			303	331722658325								
Pallet								Regular Cost			Vendor #:	_		
								Invoice Cost (WAC)	(\$)	\$112.50	Whsl. Code			
								As of date:	12/1/2024		Fineline Cod	ie:		
								7.5 or date.	12 112324		1			
											<u> </u>			
			Attach copy of SAFETY DA	TA SHEET (SE	S) or non haza	ard letter, PACKAGE IN	SERT, LABEL AND PHOTO OF I	PRODUCT PACKAGING	and BARCODE.					
*Please provide any additional inf	ormation on page	2.				See new p. 3 for De	signated Drop Ship Only.	Signa	ture:					



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

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	ii yes, indicate which.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
, ,	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS OF REGISTRY RESTRICTIONS						
	Is there a REMS on this product?						
b. Proper Shipping Name c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
e. Inhalation Hazard?	Website UKL.						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)	Omeran						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ADDII CTODAGE INFORMATION	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
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: 1-866-827-3647						
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	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  No	·						
	Special regulations or returns requirements for this product in certain states?						
Restricted to hospital, clinics, and physician offices only:  No	INU						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANEO	DUS NOTES and/or Image of Product Barcode:						



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

#### Version 2024

#### 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  b. Autofax  c. Fax  d. Phone only e. Supplier Web Site only  Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time:  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:					
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:	Overnight receipt available:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday					
	Priority Overnight receipt available:					
Class of Trade Restriction:  No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)  Comments:	PO Receipt Cut off time:  Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Information 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?					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure? Is product order for restocking purposes?					