

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

Version 2024						Introduction T	ype: New Item		x Final Version			Date:	3/11	/2025	
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.						Applicat	ion: ANDA	a. Temperati	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	DA/BLA; PMA/510	(k): 2	10500			NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room -	- between 20	and 25 C (68	° – 77° F)		
Medical Device Class, if applical															
DUNS:	11-856-3719								Other Temperature Range	Requirement					
Proprietary Name (If Applicable) a	31722-680-60	ame: D	Dimethyl Fumarate Delayed-Releas Unit of Use NDC:	se Capsules 12	0 mg and 240 m 31722-680-60		331722680608		(write in)						
Selling Unit NDC: UDI	31722-060-00		CVX Code:		31722-000-00	MVX Code:	331722000000		Notes						
Description:	Discothyd Ever and	a Dalawad Dala	ase Capsules 120 mg and 240 mg						Is this product to be shippe	d to accessors on 1			No	1	
Description:	Dimethyl Fumara	le Delayeu-Relea	ase Capsules 120 mg and 240 mg	J					Is this product to be shippe				No		
Active Ingredient(s): Dimethyl fumarate									to the product to be emppe	a to cactomore on a	.,				
									r temperature excursion qu	estions:					
URL for Additional Product Inforn		www.camberpl	harma.com						Name:		Soma Raju				
Address:	800 Centennial A Piscataway				State:	Address 2: te: NJ Zip: 08854			Number: 732-529-0423						
City: Key Contact:	Customer Service	,			Email:	-	2ip: 00004 0camberpharma.com		Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647	,			Fax:	732-562-8788	Joann Borphanna.com	c. Special re	c. Special regulations for product in any states?				No	1	
Product Therapeutic Classificatio	n:	Fumaric acid o	derivative (NRF2 activator)						Special returns requirements for this product?				No		
·										·				1	
	ADDITI	ONAL PRODUC	CT INFORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No		
The product is?			Is the Product	Direct-Ship C	Only			[]	Protect product (unit of sa	ale) from light?			No]	
a legend device?		No	Is the Product	Unit of Use		Size:	14 ct / 46 ct	e. Shelf life:					24	Months	
if yes, enter class #		la.	Orphan Drug Status				100 /010		Initial shelf life at launch	(if different):				Months	
a product kit? if yes, list NDCs of	31722-657-31: 12	No No ma 14 et	FDA Approval Status			Strength:	120 mg / 240 mg			ORDER INFORM	IATION				
component parts	31722-658-31: 24		1 DA Approvai Status				Hard gelatin, delayed-			0.052.0.00					
reverse numbered?		No				Dosage Form	release capsule		Unit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present						Bottle			2 Bottles (14		ules)	
latex-free?		Yes	Dye, Corn, Alcohol, A		s, Sugar,	Product Shap	Capsule		x Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)		
preservative-free? correctional institution block?		Yes No	Uats,	Spelt			120 mg: Light blue opaque		Ampule Glass		Minimum o	rder quantity		Yes	
opioid?		No				Product Colo	r: 240 mg: White opaque		Tube		winimum oi	rder quantity	r	res	
Cannabinoid?		No	Country of Origin	India		Book doors book	120 mg: Imprinted with 'H' on cap ar	d	Vial Liquid Sql						
If Unit Dose, is item bar coded to u	unit dose for		, ,			Product Impr	int: 'D12' on body / 240mg: Imprinted wi 'H' on cap and 'D15' on body	h	Vial Liquid Multi		If Yes, how	many of whi	ch package	type?	
hospital scanning?			Is this product covered u						Vial Powder Sgl		40	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	TAA)?	No				Vial Powder Multi			Inner/Carton	/Pack		
			FOR GENERIC DRUG PR	ODUCTO					Other: Write In			Case			
			FOR GENERIC DRUG PR	ODUCIS											
					Au	thorized Generic	*If Authorized Generic, other		Pl	HARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell uni	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Tecfidera							Each								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							(Write-in, e.g				Gram				
		DRUG SI	UPPLY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION			HCPCS J-Co	de:			Milliliter			
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes	7	GLN:	0331722498975			ITE	M AND PACKING IN	NFORMATIO	N			
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:				Weight Lbs.	Dimensi	ons (US msn	nts.)	Volume	Saleable #	
Other exemption - Write in:									weight LDS.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No	_		iginal product purc	hased	Item/Each:	0.18	3.75	2.1	3.5	27.56	1	
Is product sold by manufacturer's Has FDA granted waiver/exceptio			Yes No	+	direct from m		repackaged product	Box/Carton/i	Rundle/						
If yes, attach documentation from		oduct:	.10		i Tovide Sould	o manuracturer 10	repackageu product	Inner Pack:	Junale/						
								Case:	8.9	15.5	11.5	8	1426	40	
			GTIN AND HIBCC PRODUCT IN	NFORMATION					0.5	10.0	11.0		1420	40	
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTII	N-14	Unit of Use GTIN-14	Pallet:							
Saleable Offit of Weasure	KFID (ag(1/N)	Quantity	ПВСС		GIII	N-14	Offic of Ose G file-14								
x Item/Each	N	1			0033	31722680608	00331722680608								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESALI	ER USE ONL	.Y:	
X Case	N	40			3033	31722680609		11							
Pallet					-			Regular Cos Invoice Cost		\$112.50	Vendor #: Whsl. Code	#-			
								mvoice cost	(11.50) (4)	\$112.50	Fineline Co				
								As of date:	12/1/2024		1				
<u> </u>															
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSERT, LABEL AND PHOTO	OF PRODUCT PACK	AGING and BARCODE.						



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Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL 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? No Does the product label bear a CA Prop 65 warning? No	x 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?	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 e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
ls this product regulated for shipment by IATA?	EFA Hazaiuous waste Code.					
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number 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: DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: Yes					
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: Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?					
Comments:						
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:					



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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 Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight receipt available:
Drop Ship service fee billed with each order:	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:
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: 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/Clinic DEA #: Physician/Clinic Specialty:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?