

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

Version 2021						Introduction Type	e: New Item		x Final Version			Date:	3/8/2	2023
			PRODUCT INFORMA	TION					SPECIAL HAP	IDLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperat	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 209598							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applica									-					
DUNS:	82-677-4775								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Teriflu	unomide Tablets 14mg						(write in)					
Selling Unit NDC:	31722-247-30		Unit of Use NDC:		31722-247-30		31722247306		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Teriflunomide Tal	blets 14mg							Is this product to be shippe	d to customers on	ice?		No	1
									Is this product to be shippe	d to customers on	dry ice?		No	
Active Ingredient(s):		Teriflunomide												
						b. Contact f	or temperature excursion qu	estions:						
URL for Additional Product Inform		www.camberpharma				A dalue a a O			Name:		Soma Raju	00		
Address: City:	Piscataway	Ave (and) 800 Cente	nniai Ave, Suite 1		State:	Address 2:	ip: 08854	_	Number: Group E-mail:		732-529-04	23 <u>heterousa.co</u>		
Key Contact:	Customer Service	<u> </u>			Email:	customerservice@ca	ambernharma com		Group E-mail.		Somarajue	<u>Heterousa.co</u>	<u>III</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	amborphamia.com	c. Special re	egulations for product in any	states?			No	1
Product Therapeutic Classification		immunomodulator	v agent						Special returns requiremen				No	
l round morapound diagonicum			, -g-···						oposiai rotamo roquiromon	to for ano product.				
	ADDITI	IONAL PRODUCT IN	IFORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store pro	duct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	nly				Protect product (unit of s	ale) from light?			No	1
a legend device?		No	Is the Product	Unit of Use	, iny		30ct	e. Shelf life:	Frotect product (unit of s	ale) Irolli light?			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	3001	C. Orien inc.	Initial shelf life at launch	(if different):				Months
a product kit?		No					14mg			(,
if yes, list NDCs of			FDA Approval Status			Strength:	_			ORDER INFORI	MATION			
component parts						Dosage Form:	Tablet							
reverse numbered?		No				Doougo i oiiii			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present					_	x Bottle		1 bottle of 3			
latex-free?		Yes				Product Shape:	Round, Round Convex		Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes No					White to Off White	_	Ampule Glass		Minimum	rder quantity	.2	Yes
opioid?		No				Product Color:	Write to Oil Write		Tube		William C	ruer quaritity	<i>,</i> :	162
Cannabinoid?		No	Country of Origin	India			Debossed with 'H' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	110	,g			Product Imprint	side and 'T41'		Vial Liquid Multi		If Yes, how	many of wh	ich package i	type?
hospital scanning?			Is this product covered u	inder the					Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:		· ·	Trade Agreements Act (ГАА)?	No				Vial Power Multi			Inner/Cartor	n/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Aut		Authorized Generic, other			HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					S6	ection fields are not applicable	Rec. sell un	it to customer?	_	Rx billing u	ınit to pharm	acy:	
II. Generic Equivalent to What Bra	and?:	Aubagio										Each		
		DDUC CUDD	LY CHAIN SECURITY ACT (Deceal INFOR	MATION			(Write-in, e.	g. 1 Vial)			Gram		
		DRUG SUPP	LT CHAIN SECURITY ACT	DSCSA) INFOR	RWATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes	_	GLN:	0331722000000			ITE	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?	o o. manarara		No	_	02	0001122000000								
If ves. select exemption:					GCP:					Dimens	ions (US msi	mts \	Volume	Saleable #
Other exemption - Write in:					GCF.				Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If ves. was ori	ginal product purcha	sed	Item/Each:					T	
Is product sold by manufacturer's	s exclusive distrib	utor?	Yes		direct from mi				0.064	1.500	1.500	2.334	5.251	1
Has FDA granted waiver/exceptio	n/exemption for p	roduct?	No	7	Provide source	e manufacturer for re	epackaged product	Box/Carton/	Bundle/		_		_	_
If yes, attach documentation fro	m FDA.							Inner Pack:			_		_	_
								Case:	2.003	9.64	6.49	3.77	235.86	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION								****		
Saleable Unit of Measure	_							Pallet:	533.98	47.244	39.37	47.244	87,873.66	250
	\$	Saleable Quantity	HIBCC		GTIN		Unit of Use GTIN-14 00331722247306							
X Item/Each Box/Carton/Bundle/Inner Pack		1			0033	1722247306	00331122241306		COST INFORMATION			WHOI ESAL	ER USE ONL	γ
X Case		24			2033	1722247300			- JOOT MI ORMATION			occont	LA GOL ONE	
Pallet								Regular Cos	st		Vendor #:			
								Invoice Cos		\$50.00	Whsl. Code	e #:		
								- [1]			Fineline Co			
								As of date:			_			
								- []						
<u> </u>											<u> </u>			
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non hazar	d letter, PACKAGE IN:	SERT, LABEL AND PHOTO C	F PRODUCT PACE						
*Please provide any additional inf		_					signated Drop Ship Only.		Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD 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? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? 	No No 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?	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:	Yes Group 2 items (non-antineoplastic that meets a hazard criterion)				
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 o	r 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:	No				
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? (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#: NPI #:				
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments					
SP#		Registry: Registry Program Contact Name:	No Phone:				
ADD'L STORAGE INFORMATION		Comments					
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?:	No No	Contact tel. # if product received damaged:	1-866-827-3647				
CLASS OF TRADE RESTRICTION:	INU	Is product returnable for credit: URL/Link to returns policy:	Yes				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	' '	ervice@camberpharma.com				
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No No	product in certain states? If so, which states? Other requirements? Comments?					
Comments:							
	SCELLANEO	DUS 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 S	nip 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 #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Information Required to F	rocess PO:	Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # 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?					