

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

Version 2024						Introduction 7	ype: New Item		x Final Version			Date:	3/18/	/2025	
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*			
Company Name:	Camber Pharmac	ceuticals, Inc.				Applica	tion: ANDA	a. Temperature	- Indicate the USP temp	erature range for t	this product.				
Application Number for NDA/AN	NDA/BLA; PMA/510)(k): 210	0030			NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applical	ıble:														
DUNS:	11-856-3719								Other Temperature Range	Requirement			between 15°0	C to 30°C	
Proprietary Name (If Applicable) a		ame: Ter	nozolomide Capsules, USP 20						(write in)		(59°F to 86°	F)			
Selling Unit NDC:	31722-412-31		Unit of Use NDC:		31722-412-31	UPC: MVX Code:	331722412315		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Temozolomide Ca	apsules, USP 20 m	ng						Is this product to be shippe				No		
Active Ingredient(s):		Temozolomide, I	USP						Is this product to be shippe	d to customers on	dry ice?		No		
									b. Contact for temperature excursion questions:						
URL for Additional Product Inform Address:	mation: 800 Centennial A	www.camberpha	rma.com			Address 2:			Name:		Soma Raju 732-529-04	20			
City:	Piscataway	ve, Suite i			State:	NJ	Zip: 08854		Number: Group E-mail:			zo heterousa.coi	m		
Key Contact:	Customer Service	9			Email:	-	© camberpharma.com		Group E-mail.		30maraju 🥴	ileterousa.coi	<u> </u>		
Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u> </u>	c. Special regu	lations for product in any	states?			No	1	
Product Therapeutic Classification	on:	Alkylating agent							Special returns requiremen	ts for this product?			No		
		, , ,							.,						
	ADDITI	IONAL PRODUCT	INFORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	1	
The product is?			Is the Product	Direct-Ship	Only				Protect product (unit of sa	ale) from light?			No	1	
a legend device?		No	Is the Product	Unit of Use	,	Size:	5 ct	e. Shelf life:					24	Months	
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (if different):				Months	
a product kit?		No				Strength:	20 mg								
if yes, list NDCs of			FDA Approval Status							ORDER INFOR	MATION				
component parts reverse numbered?		No				Dosage Forn	n: Hard gelatin capsule		Unit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 5		unit:		
latex-free?		Yes					Capsule		Box/Carton			g. 1 Box of 1	0 Vials)		
preservative-free?		Yes	Alcohol, Animal Produ	cts, Dairy, Dy	e, Lactose	Product Sha	pe:		Ampule		,,	3	,		
correctional institution block?		No				Product Cole	Opaque yellow cap and		x Glass		Minimum o	rder quantity	/?	Yes	
opioid?		No				Froduct Con	opaque white body		Tube						
Cannabinoid?		No	Country of Origin	India		Product Imp	rint: Imprinted with '14' on ca	p	Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for						and 'H' on body		Vial Liquid Multi				ich package t	type?	
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (No				Vial Powder Sgl Vial Powder Multi		24	Each Inner/Cartor	/Book		
Il Ollit Dose, ilidicate NDC liele.			Trade Agreements Act (174):	INU				Other: Write In			Case	I/Fack		
FOR GENERIC DRUG PRODUCTS									Outon White in			Jouod			
			TOTA SENERIUS BROST III	0500.0											
					Au	uthorized Generic	*If Authorized Generic, other		Pł	IARMACY ORDER	R / BILL UNIT				
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit t	o customer?		Rx billing u	nit to pharm	acy:		
II. Generic Equivalent to What Bra	and?:	Temodar									Each				
								(Write-in, e.g.				Gram			
		DRUG SUF	PPLY CHAIN SECURITY ACT	DSCSA) INFO	RMATION			HCPCS J-Code				Milliliter			
Does supplier meet DSCSA defini	ition of manufactu	ror?	Yes	_	GLN:	0331722498975			J8700	AND PACKING I	NEORMATIO	N			
Is product exempt from DSCSA?		1011	No	-	GLN.	00011224909/5			1151	AAND I ACKING I	ORMATIO				
If yes, select exemption:					GCP:					Dimena	ions (US msı	nte \	Volume	Saleable #	
Other exemption - Write in:					GOF.				Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No		If yes, was o	riginal product pur	chased	Item/Each:	0.47						
Is product sold by manufacturer's	s exclusive distrib	utor?	Yes		direct from n				0.14	1.7	1.7	3	8.67	1	
Has FDA granted waiver/exception	on/exemption for p		No		Provide sour	ce manufacturer fo	r repackaged product	Box/Carton/Bu	ndle/						
If yes, attach documentation from	om FDA.							Inner Pack:							
			STIN AND HIBCC PRODUCT I	NEODMATION				Case:	3.95	11	7.5	4.5	371.25	24	
		(TIN AND HIBCC PRODUCT I	NFORMATION				Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	IN-14	Unit of Use GTIN-14	Pallet:							
	tag(1/14)	Quantity	500		311		3 3. 030 01114-14								
x Item/Each	N	1			003	31722412315	00331722412315								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	.Y:	
X Case	N	24			203	31722412319									
							-	Regular Cost			Vendor #:				
Pallet								Invoice Cost (\	VAC) (\$)	\$30.65					
Pallet								11							
Pallet								As of date:	2/25/2025		Fineline Co				
Pallet								As of date:	2/25/2025						
Pallet								As of date:	2/25/2025						
Pallet			Attach copy of SAFETY D/	ATA SHEET (S	DS) or non haza	ard letter, PACKAGE	INSERT, LABEL AND PHOTO (



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? Yes 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? 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	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: Group 1 items (antineoplastic)					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics					
(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 NO Phone: DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments					
56#	Registry: No Registry Program Contact Name: 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) 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:	Is product returnable for credit: Ves 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					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? If so, which states? Other requirements? Comments?					
Comments:						
	EOUS NOTES and/or Image of Product Barcode:					
Cytotoxic: Do not open the capsules. If a capsule is damaged, avoid inhalation or contact with your skin,	eyes, nose or mucous membranes.					



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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 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?