

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

Version 2024						Introduction 1	ype: New Ite	m		x Final Version			Date:	3/18/	2025
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Applica	ion: ANDA	Α	a. Temperature	- Indicate the USP temper	erature range for t	his product.			
Application Number for NDA/AN	DA/BLA; PMA/510	0(k): 21	0030			NDA 505(b) Type	NOT APPLICAB	BLE		Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applical	ble:														
DUNS:	11-856-3719									Other Temperature Range F	Requirement			between 15°0	C to 30°C
Proprietary Name (If Applicable) a		ame: Te	emozolomide Capsules, USP 100	) mg						(write in)		(59°F to 86°	F)		
Selling Unit NDC: UDI	31722-413-31		Unit of Use NDC:		31722-413-31	UPC: MVX Code:	331722413312			Notes					
-			CVX Code:			WVX Code.									
Description:	Temozolomide Ca	apsules, USP 100	0 mg							s this product to be shipped				No No	
Active Ingredient(s): Temozolomide, USP									Is this product to be shipped to customers on dry ice?						
								b. Contact for temperature excursion questions:							
URL for Additional Product Inform Address:	800 Centennial A	www.camberph	arma.com			Address 2:				Name:		Soma Raju 732-529-042	22		
City:	Piscataway	ive, Suite i			State:	State: NJ Zip: 08854			Number:   732-529-0423				n		
Key Contact:	Customer Service	e			Email:	-	camberpharma.com		Stroup E-mail.					<u>-</u>	
Phone Number:	1-866-827-3647				Fax:				c. Special regulations for product in any states?				No		
Product Therapeutic Classificatio	n:	Alkylating agen	t				Special returns requirements for this					duct? No			
					_										
	ADDITI	IONAL PRODUC	T INFORMATION			PRODUCT	DESCRIPTION INFORMA	ATION	d. Store produc	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only					Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	5 ct		e. Shelf life:					24	Months
if yes, enter class #		l	Orphan Drug Status						'	nitial shelf life at launch (	if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	100 mg				ORDER INFORM	AATION			
component parts			FDA Approvai Status				Hard gelatin caps	alus			ORDER IN ORK	IATION			
reverse numbered?		No				Dosage Form	n:	54.0		Jnit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 5	Capsules		
latex-free?		Yes	Alcohol, Animal Produ	cts. Dairy. Dv	e. Lactose	Product Sha	Capsule			Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	,	,,,,	,					Ampule					
correctional institution block? opioid?		No No				Product Col	Opaque pink cap opaque white boo		_	x Glass Tube		Minimum o	rder quantity	?	Yes
Cannabinoid?		No	Country of Origin	India			Imprinted with '15		-	Vial Liquid Sql					
If Unit Dose, is item bar coded to u	unit dose for	140	Country of Origin	maia		Product Imp	and 'H' on body	on oup		Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?
hospital scanning?			Is this product covered u	nder the						Vial Powder Sgl			Each		,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	ΓAA)?	No					Vial Powder Multi			Inner/Carton	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
						thorized Generic	*If Authorized Generic, o	othor		PH	ARMACY ORDER	/ BILL LINIT			
L Common Book Bodiese	AB			_	Au	unonzed Generic	section fields are not app								
I. Orange Book Rating: II. Generic Equivalent to What Bra		Temodar							Rec. sell unit to customer? Rx billing unit to pharmacy:						
ii. Generic Equivalent to what Bra	iiu:.	remodal					(Write-in, e.g. 1 Vial) Gram								
		DRUG SU	IPPLY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION				HCPCS J-Code				Milliliter		
										J8700			4		
Does supplier meet DSCSA defini	tion of manufactu	irer?	Yes		GLN:	0331722498975				ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msr	•	Volume	Saleable #
Other exemption - Write in:			No		If you was	dainal product com	hacad		Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	exclusive distrib	utor?	Yes	-	direct from m	riginal product pur	Jilased		nem/Each:	0.14	1.7	1.7	3	8.67	1
Has FDA granted waiver/exception			No				r repackaged product		Box/Carton/Bu	ndle/					
If yes, attach documentation from		_							Inner Pack:						
									Case:	3.95	11	7.5	4.5	371.25	24
			GTIN AND HIBCC PRODUCT II	NFORMATION											
Saleable Unit of Measure	DEID tog(V/N)	Colooblo	HIBCC		CTI	N-14	Unit of Use GTI	NI 14	Pallet:						
Jaieable Offit of Measure	RFID tag(Y/N)	Quantity	ПІВСС		GII	14-14	Unit of Use GTI	114-14							
x Item/Each	N	1			003	31722413312	0033172241331	12							
Box/Carton/Bundle/Inner Pack								COST INFORMATION WHOLESALER USE					Y:		
X Case	N	24			203	31722413316	]								
Pallet									Regular Cost			Vendor #:	_		
					-		-		Invoice Cost (W	/AC) (\$)	\$124.93	Whsl. Code Fineline Co			
							-		As of date:	2/25/2025		I-meime Co	uc.		
									, 10 01 date.			1			
							-					<u> </u>			
i —			Attach conv. of SAEETV DA	TA SHEET (S	DS) or non haza	rd letter PACKAGE	INSERT, LABEL AND PH	HOTO OF P	PRODUCT PACKAC	ING and BARCODE.					
			Allacir copy of SAFETT DE	TA SHEET (S	DO) OF HOIT HAZA	ild ictici, i 7toro tol	INSLITT, LABLE AND IT	1010011							



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

#### 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? 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.						



## **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	Purchase order daily receipt cut off time by supplier Cut off time:							
b. Autofax 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							
Class of Trade Restriction:	Priority Overnight receipt available:  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: 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?							