

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

Version 2024						Introduction Type	: New Item		x Final Version			Date:	3/18/	/2025
			PRODUCT INFORMAT	ION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a. Temperature	- Indicate the USP tempe	erature range for th	nis product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	(k): 210030				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:					<u> </u>			· -					
DUNS:	11-856-3719								Other Temperature Range F	Requirement	Excursions a	re permitted	between 15°C	C to 30°C
Proprietary Name (If Applicable) a		ame: Temozo	lomide Capsules, USP 250	mg					(write in)		(59°F to 86°I	-)		
Selling Unit NDC:	31722-416-31		Unit of Use NDC:		31722-416-31		1722416313		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Temozolomide Ca	apsules, USP 250 mg							Is this product to be shipped				No	
									Is this product to be shipped	d to customers on d	ry ice?		No	
Active Ingredient(s):		Temozolomide, USP						1						
URL for Additional Product Inform		www.camberpharma.c							emperature excursion que	estions:	Soma Raju			
Address:	800 Centennial A		com		1	Address 2:			Name: Number:		732-529-042	3		
City:	Piscataway	ve, oute i			State:		ip: 08854		Group E-mail:			eterousa.con	1	
Key Contact:	Customer Service	9			Email:	customerservice@ca			o. oup 2 maii.				-	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for product in any states?					1	
Product Therapeutic Classification	n:	Alkylating agent							Special returns requirement	s for this product?			No	
•					_									1
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produc	ct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	Only			1	Protect product (unit of sa	ale) from light?			No	i
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:	250 mg							
if yes, list NDCs of			FDA Approval Status			ou ongun				ORDER INFORM	IATION			
component parts		Te c				Dosage Form:	Hard gelatin capsule	1			Martin all a	NDO III		
reverse numbered? co-licensed?		No No	Allergens Present			-			Unit of Sale x Bottle		1 Bottle of 5	NDC selling	unit?	
latex-free?		140					Capsule	-	Box/Carton			g. 1 Box of 10) \/ials)	
preservative-free?		Yes Alcohol, Animal Products, Dairy, Dye, Lactose			Product Shape:	Capsule	-	Ampule		(**************************************	g. 1 DOX 01 10	, viais)		
correctional institution block?		No				Donatout Outer	Opaque white cap and		x Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:	opaque white body		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Imprinted with '18' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					1 Todact Imprint.	and 'H' on body		Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered un		-				Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (Tr	AA)?	No				Vial Powder Multi			Inner/Carton	Pack	
								L	Other: Write In			Case		
			FOR GENERIC DRUG PRO	DUCIS										
					Δ	thorized Generic *If	Authorized Generic, other		PH	IARMACY ORDER	/ BILL LINIT			
I Communication Development	AB			Т	Au		ction fields are not applicable	Dee cell unit to		ARMAOT ORDER				
I. Orange Book Rating: II. Generic Equivalent to What Brar		Temodar		1				Rec. sell unit to	customer?	1	Rx billing ui	nit to pharma Each	icy:	
ii. Generic Equivalent to What Brai	nur.	Terriodai						(Write-in, e.g. 1	Vial			Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (E	SCSA) INFOR	RMATION			HCPCS J-Code				Milliliter		
			•						J8700					
Does supplier meet DSCSA definit	tion of manufactur	rer?	Yes		GLN:	0331722498975			ITEN	AND PACKING IN	NFORMATION	١		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight I he	Dimensi	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purchas	sed	Item/Each:	0.14	1.7	1.7	3	8.67	1 1
Is product sold by manufacturer's			Yes	1	direct from m									
Has FDA granted waiver/exception		roduct?	No		Provide source	ce manufacturer for re	packaged product	Box/Carton/Bu	ndle/					
If yes, attach documentation fron	n FDA.							Inner Pack: Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION				Case.	3.95	11	7.5	4.5	371.25	24
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTII	N-14	Unit of Use GTIN-14							
		Quantity												
x Item/Each	N	1			0033	31722416313	00331722416313							
Box/Carton/Bundle/Inner Pack									COST INFORMATION		,	WHOLESALE	R USE ONL	.Y:
X Case	N	24			2033	31722416317		B			Vander #			
Pallet								Regular Cost Invoice Cost (V	VAC) (\$)	\$255.71	Vendor #: Whsl. Code	#-		
								voice cost (v	·AO) (4)	φ200./1	Fineline Code			
								As of date:	2/25/2025		1			
								1			1			
*Please provide any additional info	I		Attach copy of SAFETY DAT	TA SHEET (SE	S) or non haza		SERT, LABEL AND PHOTO OF P	RODUCT PACKAG	GING and BARCODE.					



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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?