

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

						Introduction Type:	New Item	X	Final Version			Date:	3/10/	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac					Application:	ANDA	a. Temperature – Indica	ate the USP tempe					
Application Number for NDA/ANI	DA/BLA; PMA/510	(k): 210030				NDA 505(b) Type:	NOT APPLICABLE		iture Range	Controlled Room -		and 25 C (68	s° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719								mperature Range F				between 15°0	C to 30°C
Proprietary Name (If Applicable) a		ime: Temozo	olomide Capsules, USP 140		1700 111	Luce 1			ite in)		(59°F to 86°	F)		
Selling Unit NDC: UDI	31722-414-14		Unit of Use NDC:	3	31722-414-14	UPC: 3317 MVX Code:	22414142	Notes						
	_		CVX Code:			mvA code.		<u> </u>			_			
Description:	Temozolomide Ca	apsules, USP 140 mg							oduct to be shipped				No	l
Active Ingredient(s):		Temozolomide, USP	1					is this pro	oduct to be shipped	to customers on a	y ice?		No	l .
Active ingredient(s).		Terriozolorniae, OSI						b. Contact for temperat	ture excursion au	stions:				
URL for Additional Product Inform	ation:	www.camberpharma.	.com					Name:	ano oxoanoion que		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:		Number:	:		732-529-042			
City:	Piscataway				State:		: 08854	Group E	-mail:		somaraju@h	neterousa.com	<u>n</u>	
Key Contact:	Customer Service	!			Email: Fax:	customerservice@cam	berpharma.com						No	I
Phone Number:	1-866-827-3647	Allo detine e e e e e			rax:	732-562-8788		c. Special regulations f						
Product Therapeutic Classification	n:	Alkylating agent						Special r	eturns requirement	s for this product?			No	1
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit of	of cale) unright?				No	ĺ
The mandred in 0	ADDITI	SNAL PRODUCT IN		Diseast Chin On	le e	PRODUCT DESC	INTERIOR IN CRIMATION	- I I		I-) f l'-l-(0				İ
The product is? a legend device?		No	Is the Product	Direct-Ship On Unit of Use	ıy		14 ct	e. Shelf life:	product (unit of sa	ie) from light?			No 24	Months
if yes, enter class #		INO	Orphan Drug Status	Offic of Ose		Size:	14 61		elf life at launch (i	f different)			24	Months
a product kit?		No	o.p.ian D. ag otatao				140 mg		.oo ut iuu.io (i					
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts						Dosage Form:	Hard gelatin capsule							
reverse numbered?		No				Doougo I o.i.i.		Unit of S				NDC selling	unit?	
co-licensed? latex-free?		No	Allergens Present				Capsule		Bottle Box/Carton		1 Bottle of 1	4 Capsules g. 1 Box of 10	0 \/:ala\	
preservative-free?		Yes Yes	Alcohol, Animal Produ	ıcts, Dairy, Dye, I	Lactose	Product Shape:	Capsule		Ampule		(vviite-in, e.	g. 1 Box 01 10	u viais)	
correctional institution block?		No					Opaque blue cap and		Glass		Minimum o	der quantity	1?	Yes
opioid?		No				Product Color:	opaque white body		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Imprinted with '16' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					i roddot imprint.	and 'H' on body		Vial Liquid Multi				ch package	ype?
hospital scanning?			Is this product covered u						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	No				Vial Powder Multi Other: Write In			Inner/Carton Case	/Pack	
			FOR GENERIC DRUG PR	ODUCTS					Other. Write in			Case		
			FOR GENERIC DRUG FR	ODUCIS										
				Γ	Au	thorized Generic *If A	uthorized Generic, other		PH	ARMACY ORDER	BILL UNIT			
I. Orange Book Rating:	AB						on fields are not applicable	Rec. sell unit to custon	ner?		Rx hilling u	nit to pharma	acv.	
II. Generic Equivalent to What Bran												Each	,-	
·		Temodar												
				_				(Write-in, e.g. 1 Vial)				Gram		
			Y CHAIN SECURITY ACT ((DSCSA) INFORM	MATION			HCPCS J-Code:						
		DRUG SUPPLY						(Write-in, e.g. 1 Vial) HCPCS J-Code:		AND BACKING IN		Gram Milliliter		
Does supplier meet DSCSA definit	tion of manufactu	DRUG SUPPLY	Yes		MATION	0331722498975		HCPCS J-Code:		AND PACKING IN	FORMATIO	Gram Milliliter		
Is product exempt from DSCSA?	tion of manufactu	DRUG SUPPLY			GLN:	0331722498975		HCPCS J-Code:				Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption:	tion of manufactu	DRUG SUPPLY	Yes			0331722498975		HCPCS J-Code:		Dimensio	ons (US msn	Gram Milliliter	Volume (Cuba)	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	tion of manufactu	DRUG SUPPLY	Yes No		GLN: GCP:		d	HCPCS J-Code: J8700	Weight Lbs.	Dimensio Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		DRUG SUPPLY	Yes		GLN: GCP:	iginal product purchase	d	HCPCS J-Code:	ITEM	Dimensio	ons (US msn	Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	exclusive distribu	DRUG SUPPLY	Yes No		GLN: GCP: f yes, was or direct from m	iginal product purchase		HCPCS J-Code: J8700	Weight Lbs.	Dimensio Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	exclusive distribu	DRUG SUPPLY	Yes No No Yes		GLN: GCP: f yes, was or direct from m	iginal product purchase		HCPCS J-Code: J8700 Item/Each: Box/Carton/Bundle/ Inner Pack:	Veight Lbs.	Dimensio Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	exclusive distribu	DRUG SUPPLY	Yes No No Yes No		GLN: GCP: f yes, was or direct from m	iginal product purchase		HCPCS J-Code: J8700 litem/Each: Box/Carton/Bundle/	Veight Lbs.	Dimensio Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron	exclusive distribu n/exemption for pr n FDA.	DRUG SUPPLY rer? utor? roduct?	Yes No No Yes No And HIBCC PRODUCT II		GLN: GCP: If yes, was or direct from m Provide source	iginal product purchase fr? ce manufacturer for repa	ackaged product	HCPCS J-Code: J8700 Item/Each: Box/Carton/Bundle/ Inner Pack:	Weight Lbs.	Dimension Depth 1.7	ons (US msn Width 1.7	Gram Milliliter	(Cube) 8.67	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	exclusive distribu	DRUG SUPPLY rer? utor? roduct? GTIN Saleable	Yes No No Yes No		GLN: GCP: f yes, was or direct from m	iginal product purchase fr? ce manufacturer for repa		Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs.	Dimension Depth 1.7	ons (US msn Width 1.7	Gram Milliliter	(Cube) 8.67	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron	exclusive distribu n/exemption for pr n FDA.	DRUG SUPPLY rer? utor? roduct?	Yes No No Yes No And HIBCC PRODUCT II		GLN: GCP: f yes, was or direct from m Provide source GTII	iginal product purchase fr? ce manufacturer for repa	ackaged product	Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs.	Dimension Depth 1.7	ons (US msn Width 1.7	Gram Milliliter	(Cube) 8.67	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure	exclusive distribution/exemption for pun FDA. RFID tag(Y/N)	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity 1	Yes No No Yes No And HIBCC PRODUCT II		GLN: GCP: f yes, was or direct from m Provide source GTII	iginal product purchase fr? the manufacturer for repair N-14	Unit of Use GTIN-14	Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs.	Dimension Depth 1.7	ons (US msn Width 1.7 7.5	Gram Milliliter N nts.) Height 3	(Cube) 8.67	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distribution/exemption for pun FDA. RFID tag(Y/N)	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity	Yes No No Yes No And HIBCC PRODUCT II		GLN: GCP: f yes, was or direct from m Provide source GTII	iginal product purchase fr? se manufacturer for repa	Unit of Use GTIN-14	HCPCS J-Code: J8700 Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: Coss	Weight Lbs. 0.14 3.95	Dimension Depth 1.7	nns (US msn Width 1.7 7.5	Gram Milliliter N nts.) Height 3	(Cube) 8.67 371.25	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distribution/exemption for print FDA. RFID tag(Y/N)	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity 1	Yes No No Yes No And HIBCC PRODUCT II		GLN: GCP: f yes, was or direct from m Provide source GTII	iginal product purchase fr? the manufacturer for repair N-14	Unit of Use GTIN-14	HCPCS J-Code: J8700 Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: COS	Weight Lbs. 0.14 3.95	Dimension Depth 1.7	vendor#:	Gram Milliliter N Ints.) Height 3 4.5	(Cube) 8.67 371.25	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distribution/exemption for print FDA. RFID tag(Y/N)	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity 1	Yes No No Yes No And HIBCC PRODUCT II		GLN: GCP: f yes, was or direct from m Provide source GTII	iginal product purchase fr? the manufacturer for repair N-14	Unit of Use GTIN-14	HCPCS J-Code: J8700 Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: Coss	Weight Lbs. 0.14 3.95	Dimension Depth 1.7	vendor #:	Gram Milliliter N Height 3 4.5	(Cube) 8.67 371.25	Pieces 1 24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distribution/exemption for print FDA. RFID tag(Y/N)	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity 1	Yes No No Yes No And HIBCC PRODUCT II		GLN: GCP: f yes, was or direct from m Provide source GTII	iginal product purchase fr? the manufacturer for repair N-14	Unit of Use GTIN-14	HCPCS J-Code: J8700 Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: COS: Regular Cost Invoice Cost (WAC) (\$)	Weight Lbs. 0.14 3.95	Dimension Depth 1.7	vendor#:	Gram Milliliter N Height 3 4.5	(Cube) 8.67 371.25	Pieces 1 24
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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H.	AZARD 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?