



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 3/18/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
<b>Company Name:</b> Camber Pharmaceuticals, Inc.				<b>Application:</b> ANDA			
<b>Application Number for NDA/ANDA/BLA; PMA/510(k):</b> 210030				<b>NDA 505(b) Type:</b> NOT APPLICABLE			
<b>Medical Device Class, if applicable:</b>							
<b>DUNS:</b> 11-856-3719							
<b>Proprietary Name (If Applicable) and Established Name:</b> Temozolomide Capsules, USP 180 mg							
<b>Selling Unit NDC:</b> 31722-415-31				<b>Unit of Use NDC:</b> 31722-415-31		<b>UPC:</b> 331722415316	
<b>UDI</b>				<b>CVX Code:</b>		<b>MVX Code:</b>	
<b>Description:</b> Temozolomide Capsules, USP 180 mg							
<b>Active Ingredient(s):</b> Temozolomide, USP							
<b>URL for Additional Product Information:</b> <a href="http://www.camberpharma.com">www.camberpharma.com</a>							
<b>Address:</b> 800 Centennial Ave, Suite 1				<b>Address 2:</b>			
<b>City:</b> Piscataway				<b>State:</b> NJ		<b>Zip:</b> 08854	
<b>Key Contact:</b> Customer Service				<b>Email:</b> <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a>			
<b>Phone Number:</b> 1-866-827-3647				<b>Fax:</b> 732-562-8788			
<b>Product Therapeutic Classification:</b> Alkylating agent							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
<b>The product is?</b>		<b>Is the Product...</b>		<b>Size:</b>		<b>5 ct</b>	
<b>a legend device?</b>		<b>Is the Product...</b>		<b>Strength:</b>		<b>180 mg</b>	
<b>if yes, enter class #</b>		<b>Orphan Drug Status</b>		<b>Dosage Form:</b>		<b>Hard gelatin capsule</b>	
<b>a product kit?</b>				<b>Product Shape:</b>		<b>Capsule</b>	
<b>if yes, list NDCs of component parts</b>		<b>FDA Approval Status</b>		<b>Product Color:</b>		<b>Opaque orange cap and opaque white body</b>	
<b>reverse numbered?</b>				<b>Product Imprint:</b>		<b>Imprinted with '17' on cap and 'H' on body</b>	
<b>co-licensed?</b>							
<b>latex-free?</b>		<b>Allergens Present</b>					
<b>preservative-free?</b>		<b>Alcohol, Animal Products, Dairy, Dye, Lactose</b>					
<b>correctional institution block?</b>		<b>Country of Origin</b>		<b>India</b>			
<b>opioid?</b>							
<b>Cannabinoid?</b>							
<b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b>		<b>Is this product covered under the Trade Agreements Act (TAA)?</b>		<b>No</b>			
<b>If Unit Dose, indicate NDC here:</b>							
FOR GENERIC DRUG PRODUCTS							
<b>I. Orange Book Rating:</b> AB				<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable			
<b>II. Generic Equivalent to What Brand?:</b> Temodar							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
<b>Does supplier meet DSCSA definition of manufacturer?</b>				<b>GLN:</b> 0331722498975			
<b>Is product exempt from DSCSA?</b>							
<b>If yes, select exemption:</b>				<b>GCP:</b>			
<b>Other exemption - Write in:</b>							
<b>Is product repackaged?</b>				<b>If yes, was original product purchased direct from mfr?</b>			
<b>Is product sold by manufacturer's exclusive distributor?</b>				<b>Provide source manufacturer for repackaged product</b>			
<b>Has FDA granted waiver/exception/exemption for product?</b>							
<b>If yes, attach documentation from FDA.</b>							
GTIN AND HIBCC PRODUCT INFORMATION							
<b>Saleable Unit of Measure</b>		<b>RFID tag(Y/N)</b>	<b>Saleable Quantity</b>	<b>HIBCC</b>	<b>GTIN-14</b>	<b>Unit of Use GTIN-14</b>	
<input checked="" type="checkbox"/> Item/Each		N	1		00331722415316	00331722415316	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		N	24		20331722415310		
<input checked="" type="checkbox"/> Case							
<input checked="" type="checkbox"/> Pallet							
<b>ITEM AND PACKING INFORMATION</b>							
	<b>Weight Lbs.</b>	<b>Dimensions (US msmts.)</b>			<b>Volume (Cube)</b>	<b>Saleable # Pieces</b>	
		<b>Depth</b>	<b>Width</b>	<b>Height</b>			
<b>Item/Each:</b>	0.14	1.7	1.7	2.9	8.38	1	
<b>Box/ Carton/ Bundle/ Inner Pack:</b>							
<b>Case:</b>	3.95	11	7.5	4.3	354.75	24	
<b>Pallet:</b>							
COST INFORMATION				WHOLESALE USE ONLY:			
<b>Regular Cost</b>				<b>Vendor #:</b>			
<b>Invoice Cost (WAC) (\$)</b>				<b>Whsl. Code #:</b>			
As of date: 2/25/2025				<b>Fineline Code:</b>			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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?  
Is the product a CA Prop 65 carcinogen? ☐ No  
Is the product a CA Prop 65 reproductive toxicant? ☐ No  
Does the product label bear a CA Prop 65 warning? ☐ No

- c. Contact Hazard? ☐ Yes
- d. Does this product require special clean-up instructions?  
(If yes, attach SDS with special instructions.) ☐ Yes
- e. Does the product contain DEHP? ☐ No

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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? ☐ No

Is this product regulated for shipment by IATA?  
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard? ☐ No

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

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)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);  
SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? ☐ No Controlled Substance Code
- Controlled by State(s)? ☐ No Listed Chemical (List I or II) ☐ No
- ARCOS Reportable? ☐ No If yes, indicate which:
- Schedule No.  Is it a scheduled listed chemical product?: ☐ No

### CLASS OF TRADE RESTRICTION:

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:

### SDS Hazard Classification

- ☒ Organic ☐ Corrosive
- ☐ Inorganic ☐ Oxidizer
- ☐ Steroid/Androgen ☐ Contact Hazard

Does the product have an Aerosol class? If yes,  
identify NFPA Storage Level:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

Yes

If yes, indicate which:

Group 1 items (antineoplastic)

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

No

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

#### 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 #:

Comments

#### Registry:

No

Registry Program Contact Name:

Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

1-866-827-3647

Is product returnable for credit:

Yes

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this  
product in certain states?

No

If so, which states? Other requirements? Comments?

### MISCELLANEOUS 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.

Release DATE



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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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p><b>Class of Trade Restriction:</b></p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p><b>Other Data Information Required to Process PO:</b></p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>