



# 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 140 mg							
<b>Selling Unit NDC:</b> 31722-414-14				<b>Unit of Use NDC:</b> 31722-414-14		<b>UPC:</b> 331722414142	
<b>UDI</b>				<b>CVX Code:</b>		<b>MVX Code:</b>	
<b>Description:</b> Temozolomide Capsules, USP 140 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>			
a legend device?		Direct-Ship Only		14 ct			
if yes, enter class #		Unit of Use					
a product kit?		Orphan Drug Status		Strength:		140 mg	
if yes, list NDCs of component parts				Dosage Form:		Hard gelatin capsule	
reverse numbered?		FDA Approval Status		Product Shape:		Capsule	
co-licensed?				Product Color:		Opaque blue cap and opaque white body	
latex-free?		Allergens Present		Product Imprint:		Imprinted with '16' on cap and 'H' on body	
preservative-free?		Alcohol, Animal Products, Dairy, Dye, Lactose					
correctional institution block?		Country of Origin					
opioid?		India					
Cannabinoid?							
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?					
If Unit Dose, indicate NDC here:		No					
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			
Is product exempt from DSCSA?							
If yes, select exemption:				<b>GCP:</b>			
Other exemption - Write in:							
Is product repackaged?				If yes, was original product purchased direct from mfr?			
Is product sold by manufacturer's exclusive distributor?				Provide source manufacturer for repackaged product			
Has FDA granted waiver/exception/exemption for product?							
If yes, attach documentation from FDA.							
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		00331722414142	00331722414142	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		N	24		20331722414146		
<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	3	8.67	1	
<b>Box/ Carton/ Bundle/ Inner Pack:</b>							
<b>Case:</b>	3.95	11	7.5	4.5	371.25	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:



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

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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?

No

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?

c. Contact Hazard?

Yes

d. Does this product require special clean-up instructions?

Yes

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

No

Is this product regulated for shipment by DOT?

No

(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?

Is this product regulated for shipment by IATA?

No

(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?

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

No

☐ 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

Yes

Restricted to retail pharmacy only:

No

Restricted to hospital, clinics, and physician offices only:

No

Restricted from US territories? (explain in comments)

No

Comments:

### SDS Hazard Classification

☒

Organic

☐

Inorganic

☐

Steroid/Androgen

☐

Corrosive

☐

Oxidizer

☐

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:

No

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned

NCPDP#:

by Supplier:

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="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></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="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></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="checkbox"/></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="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></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="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></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="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></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="checkbox"/></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="checkbox"/></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="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>