



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

Version 2024 Introduction Type:   Final Version Date:

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA  
**Application Number for NDA/ANDA/BLA; PMA/510(k):** 209267 **NDA 505(b) Type:** NOT APPLICABLE  
**Medical Device Class, if applicable:** \_\_\_\_\_  
**DUNS:** 11-856-3719  
**Proprietary Name (If Applicable) and Established Name:** Erlotinib Tablets 100 mg  
**Selling Unit NDC:** 31722-264-30 **Unit of Use NDC:** 31722-264-30 **UPC:** 331722264303  
**UDI** \_\_\_\_\_ **CVX Code:** \_\_\_\_\_ **MX Code:** \_\_\_\_\_  
**Description:** Erlotinib Tablets 100 mg  
**Active Ingredient(s):** Erlotinib hydrochloride  
**URL for Additional Product Information:** [www.camberpharma.com](http://www.camberpharma.com)  
**Address:** 800 Centennial Ave, Suite 1 **Address 2:** \_\_\_\_\_  
**City:** Piscataway **State:** NJ **Zip:** 08854  
**Key Contact:** Customer Service **Email:** [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)  
**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788  
**Product Therapeutic Classification:** Kinase inhibitor

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range:   
 Other Temperature Range Requirement (write in): \_\_\_\_\_  
 Notes: \_\_\_\_\_  
 Is this product to be shipped to customers on ice?   
 Is this product to be shipped to customers on dry ice?   
**b. Contact for temperature excursion questions:**  
**Name:** Soma Raju  
**Number:** 732-529-0423  
**Group E-mail:** [somaraju@heterousa.com](mailto:somaraju@heterousa.com)  
**c. Special regulations for product in any states?**  
 Special returns requirements for this product?   
**d. Store product (unit of sale) upright?**   
**Protect product (unit of sale) from light?**   
**e. Shelf life:**  Months  
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device?	<input type="text" value="No"/>	Is the Product... Is the Product... Orphan Drug Status	Direct-Ship Only Unit of Use <input type="text"/>
if yes, enter class # a product kit?	<input type="text" value="No"/>	FDA Approval Status	Size: <input type="text" value="30 ct"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text"/>	Allergens Present	Strength: <input type="text" value="100 mg"/>
co-licensed?	<input type="text" value="No"/>	<input type="text" value="Dairy, Lactose"/>	Dosage Form: <input type="text" value="Film-coated tablet"/>
latex-free?	<input type="text" value="Yes"/>	Country of Origin	Product Shape: <input type="text" value="Round, biconvex"/>
preservative-free?	<input type="text" value="Yes"/>	<input type="text" value="India"/>	Product Color: <input type="text" value="White"/>
opioid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	Product Imprint: <input type="text" value="Debossed with 'H' on one side&lt;br/&gt;and '21' on the other side"/>
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 30 Tablets"/>
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="1"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/>
<input type="checkbox"/> Vial Powder Multi	<input type="text"/>
<input type="checkbox"/> Other: Write In	<input type="text"/>

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:  Authorized Generic  \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?:

**PHARMACY ORDER / BILL UNIT**

**Rec. sell unit to customer?**

**Rx billing unit to pharmacy:**  
 Each  
 Gram  
 Milliliter  
**HCPCS J-Code:**

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?   
 Is product exempt from DSCSA?   
 If yes, select exemption:  
 Other exemption - Write in: \_\_\_\_\_  
 Is product repackaged?   
 Is product sold by manufacturer's exclusive distributor?   
 Has FDA granted waiver/exception/exemption for product?   
 If yes, attach documentation from FDA. \_\_\_\_\_

**GLN:**   
**GCP:**

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product: \_\_\_\_\_

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.12	2.2	1.8	3.5	13.86	1
Box/Carton/Bundle/ Inner Pack:						
Case:	3.6	11.25	9.25	4.25	442.27	24
Pallet:						

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722264303	00331722264303
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack					
<input checked="" type="checkbox"/> Case	N	24		20331722264307	
<input type="checkbox"/> Pallet					

**COST INFORMATION** **WHOLESALE USE ONLY:**

**Regular Cost**

**Invoice Cost (WAC) (\$)**

**As of date:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**

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?  No
- 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?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- 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?

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?

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  Yes  Controlled Substance Code
- Controlled by State(s)?  No  Yes  Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes
- Schedule No.  If it is a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify  No

NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  Yes  No

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  Yes

If Yes, is it managed with a pharmacy registry?  No  Yes

Website URL:

Med Guide Required  No  Yes

Limited Distribution Requirement

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

**REMS:**  No  Yes

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  NCPDP#:  NPI #:

Comments

**Registry:**  No  Yes

Registry Program Contact Name:  Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647

Is product returnable for credit:  Yes  No

URL/Link to returns policy:  contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No  Yes

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:



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