



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 25 mg
Selling Unit NDC: 31722-263-30 **Unit of Use NDC:** 31722-263-30 **UPC:** 331722263306
UDI _____ **CVX Code:** _____ **MX Code:** _____
Description: Erlotinib Tablets 25 mg
Active Ingredient(s): Erlotinib hydrochloride
URL for Additional Product Information: 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
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:
Number:
Group E-mail:
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="25 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"/>
correctional institution block? 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
and '28' 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	<input type="text" value="(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	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="1"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="text"/>
<input type="checkbox"/> Other: Write In	<input type="text" value="Inner/Carton/Pack"/>
	<input type="text" value="Case"/>

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
 HCPSC 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		
Box/Carton/Bundle/Inner Pack:	0.11	2.2	1.8	3.5	13.86	1
Case:	3.25	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		00331722263306	00331722263306
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack					
<input checked="" type="checkbox"/> Case	N	24		20331722263300	
<input type="checkbox"/> Pallet					

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost
 Invoice Cost (WAC) (\$)
 As of date:
Vendor #:
Whsl. Code #:
Fineline Code:

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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? 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 No
- Cargo No
- Passenger & Cargo No

Is this a reportable quantity? NoRQ 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 If yes, indicate which:
- Schedule No. Is it 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 Corrosive
- Inorganic Oxidizer
- Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, identify NoNFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? Yes NoIf 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 YesIf Yes, is it managed with a pharmacy registry? No YesWebsite URL: Med Guide Required No YesLimited Distribution Requirement No YesComments / Details: (For example, iPledge program?) **REMS:** No YesREMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: No YesWholesale distributor support: No YesProvider Name: DEA #: Site Enrollment Number assigned by Supplier: NCPDP#: NPI #: Comments **Registry:** No YesRegistry Program Contact Name: Phone: Comments **RETURN INSTRUCTIONS**Contact tel. # if product received damaged: 1-866-827-3647Is product returnable for credit: Yes NoURL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No YesIf so, which states? Other requirements? Comments? **MISCELLANEOUS NOTES and/or Image of Product Barcode:**



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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 <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"/>	Purchase order daily receipt cut off time by supplier 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"/>	Overnight receipt available: <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 Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <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"/>