



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

Version 2024 Introduction Type:  New Item  Final Version Date: 7/15/2024

**PRODUCT INFORMATION**

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA; PMA/510(k): 205504 NDA 505(b) Type: NOT APPLICABLE  
 Medical Device Class, if applicable:  
 DUNS: 11-856-3719  
 Proprietary Name (If Applicable) and Established Name: Eszopiclone Tablets, USP 1 mg  
 Selling Unit NDC: 31722-855-30 Unit of Use NDC: 31722-855-30 UPC: 331722855303  
 UDI  
 CVX Code: MVX Code:  
 Description: Eszopiclone Tablets, USP 1 mg  
 Active Ingredient(s): Eszopiclone, USP  
 URL for Additional Product Information: [www.camberpharma.com](http://www.camberpharma.com)  
 Address: 800 Centennial Ave, Suite 1 State: NJ Address 2:  
 City: Piscataway 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: Sedative-hypnotic

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)  
 Other Temperature Range Requirement (write in):  
 Notes:  
 Is this product to be shipped to customers on ice?  No  
 Is this product to be shipped to customers on dry ice?  No  
 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?  \*Yes  
 Special returns requirements for this product?  No  
 d. Store product (unit of sale) upright?  No  
 Protect product (unit of sale) from light?  No  
 e. Shelf life:  24 Months  
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? if yes, enter class #	<input type="checkbox"/> No	Is the Product... Is the Product... Orphan Drug Status	Direct-Ship Only Unit of Use
if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	FDA Approval Status	Size: 30 ct
co-licensed?	<input type="checkbox"/> No	Allergens Present	Strength: 1 mg
latex-free?	<input checked="" type="checkbox"/> Yes	Dairy, Lactose, Casein	Dosage Form: Film-coated tablet
preservative-free?	<input checked="" type="checkbox"/> Yes	Country of Origin	Product Shape: Round, biconvex
correctional institution block? opioid?	<input type="checkbox"/> No	India	Product Color: Light blue
Cannabinoid?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	Product Imprint: Debossed with 'H' on one side and 'E14' on the other side
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
If Unit Dose, indicate NDC here:	<input type="checkbox"/>		

**ORDER INFORMATION**

Unit of Sale:  Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Powder Multi  
 Other: Write In  
 What is the NDC selling unit?  
 1 Bottle of 30 Tablets  
 (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity?  Yes  
 If Yes, how many of which package type?  
 24 Each  
 Inner/Carton/Pack  
 Case

**FOR GENERIC DRUG PRODUCTS**

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

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?  Each  
 Gram  
 Milliliter  
 Rx billing unit to pharmacy:  
 (Write-in, e.g. 1 Vial)  
 HCPCS J-Code:

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

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 Is product exempt from DSCSA?  
 If yes, select exemption:  
 Other exemption - Write in:  
 Is product repackaged?  No  
 Is product sold by manufacturer's exclusive distributor?  Yes  
 Has FDA granted waiver/exception/exemption for product?  No  
 If yes, attach documentation from FDA.  
 GLN: 860000397957  
 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:	0.05	1.5	1.5	3	6.75	1
Case:	1.8	9.5	6.5	4	247	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		00331722855303	00331722855303
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack					
<input checked="" type="checkbox"/> Case	N	24		30331722855304	
<input type="checkbox"/> Pallet					

**COST INFORMATION**

Regular Cost  
 Invoice Cost (WAC) (\$) \$4.80  
 As of date: 6/12/2024  
**WHOLESALE USE ONLY:**  
 Vendor #:  
 Whsl. Code #:  
 Fineline Code:



# 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?  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?  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  No
- 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?  Yes  No  Controlled Substance Code: 2784
- Controlled by State(s)?  Yes  No  Listed Chemical (List I or II)  No
- ARCOS Reportable?  Yes  No  If yes, indicate which:
- Schedule No.  4  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  No
- 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  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?  No  
If yes, indicate which:

### 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 by Supplier:  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  No

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:

\*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.



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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> <ul style="list-style-type: none"><li>a. EDI <input type="checkbox"/></li><li>b. Autofax <input type="checkbox"/></li><li>c. Fax <input type="checkbox"/></li><li>d. Phone only <input type="checkbox"/></li><li>e. Supplier Web Site only <input type="checkbox"/></li></ul> <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> <ul style="list-style-type: none"><li><input type="checkbox"/> Monday</li><li><input type="checkbox"/> Tuesday</li><li><input type="checkbox"/> Wednesday</li><li><input type="checkbox"/> Thursday</li><li><input type="checkbox"/> Friday</li></ul> <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>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>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>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>
<p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>	