



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

Version 2024

Introduction Type: New Item☒ Final Version

Date: 5/5/2025

PRODUCT INFORMATION

Company Name:	Camber Pharmaceuticals, Inc.	Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	211186	NDA 505(b) Type:	NOT APPLICABLE
Medical Device Class, if applicable:			
DUNS:	11-856-3719		
Proprietary Name (If Applicable) and Established Name:	Eslicarbazepine Acetate Tablets 800 mg		
Selling Unit NDC:	31722-431-30	Unit of Use NDC:	31722-431-30
UDI		CVX Code:	
		UPC:	331722431309
		MVX Code:	
Description:	Eslicarbazepine Acetate Tablets 800 mg		
Active Ingredient(s):	Eslicarbazepine acetate		
URL for Additional Product Information:	www.camberpharma.com		
Address:	800 Centennial Ave, Suite 1	Address 2:	
City:	Piscataway	State:	NJ
Key Contact:	Customer Service	Zip:	08854
Phone Number:	1-866-827-3647	Email:	customerservice@camberpharma.com
		Fax:	732-562-8788
Product Therapeutic Classification:	Anticonvulsant		

ADDITIONAL PRODUCT INFORMATION

The product is?		Is the Product...	Direct-Ship Only
a legend device?	No	Is the Product...	Unit of Use
if yes, enter class #		Orphan Drug Status	
a product kit?	No	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	
reverse numbered?	No	Alcohol	
co-licensed?	No	Country of Origin	India
latex-free?	Yes	Is this product covered under the Trade Agreements Act (TAA)?	No
preservative-free?	Yes		
corrective institution block?	No		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is it bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			

PRODUCT DESCRIPTION INFORMATION

Size:	30 ct
Strength:	800 mg
Dosage Form:	Tablet
Product Shape:	Oblong, with functional scoring on both sides
Product Color:	White to off-white
Product Imprint:	Engraved with 'E34' on one side and 'H' on the other side

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:	AB	<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	Aptiom		

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	0031722498975
Is product exempt from DSCSA?	No	GCP:	
If yes, select exemption:		If yes, was original product purchased direct from mfr?	
Other exemption - Write in:		Provide source manufacturer for repackaged product	
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.			

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		00331722431309	00331722431309
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack					
<input checked="" type="checkbox"/> Case	N	24		20331722431303	
<input type="checkbox"/> Pallet					

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)	Excursions permitted between 15°C to 30°C (59°F to 86°F).
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
c. Special regulations for product in any states?	No
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

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	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	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	24 Each
	Inner/ Carton/ Pack
	Case

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.06	1.63	1.63	3.33	8.85	1
Case:	1.64	10.75	7.5	4.5	362.81	24
Pallet:						

COST INFORMATION

Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$218.20	Whsl. Code #:	
As of date:	5/6/2025	Fineline Code:	

WHOLESALE USE ONLY:

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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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?	<input type="checkbox"/> No		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/> No		
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/> No		
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/> No		
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/> No		
c. Contact Hazard?	<input type="checkbox"/> No		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/> No		
e. Does the product contain DEHP?	<input type="checkbox"/> No		
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text"/>		
b. Proper Shipping Name	<input type="text"/>		
c. DOT Hazard Class	<input type="text"/>		
d. Packing Group	<input type="text"/>		
e. Inhalation Hazard?	<input type="checkbox"/>		
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text"/>		
b. Proper Shipping Name	<input type="text"/>		
c. DOT Hazard Class	<input type="text"/>		
d. Packing Group	<input type="text"/>		
e. Inhalation Hazard?	<input type="checkbox"/>		
Is the product restricted for air shipment? If so, indicate restriction:		<input type="checkbox"/> No	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
Is this a reportable quantity? <input type="checkbox"/> No			
RQ Threshold: <input type="text"/>			
Is this a marine pollutant? <input type="checkbox"/> No			
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
<input type="checkbox"/> No (if yes, identify method below)			
<input type="checkbox"/> Limited Quantity			
<input type="checkbox"/> Consumer Commodity, ORM-D			
<input type="checkbox"/> Small Quantity (49 CFR 173.4)			
<input type="checkbox"/> Special Permit; DOT-SP			
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP# <input type="text"/>			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	<input type="text"/>
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	<input type="text"/>
Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="checkbox"/> Yes	
Restricted to retail pharmacy only:		<input type="checkbox"/> No	
Restricted to hospital, clinics, and physician offices only:		<input type="checkbox"/> No	
Restricted from US territories? (explain in comments)		<input type="checkbox"/> No	
Comments: <input type="text"/>			
SDS Hazard Classification			
<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive		
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer		
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard		
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:		<input type="checkbox"/> No	
NFPA Storage Level:		<input type="text"/>	
Is the product a NIOSH hazardous drug?		<input type="checkbox"/> No	
If yes, indicate which:		<input type="text"/>	
Hazardous Waste Identification			
EPA Hazardous Waste Code:		Waste Characteristics <input type="text"/>	
REMS or REGISTRY RESTRICTIONS			
Is there a REMS on this product?		<input type="checkbox"/> No	
If Yes, is it managed with a pharmacy registry?		<input type="text"/>	
Website URL:		<input type="text"/>	
Med Guide Required		<input type="checkbox"/> No	
Limited Distribution Requirement		<input type="text"/>	
Comments / Details: (For example, iPledge program?)		<input type="text"/>	
REMS:		<input type="checkbox"/> No	
REMS Program Manager Name:		Phone: <input type="text"/>	
Supplier Manages REMS registry exclusively:		<input type="text"/>	
Wholesale distributor support:		<input type="text"/>	
Provider Name:		DEA #: <input type="text"/>	
Site Enrollment Number assigned by Supplier:		NCPDP#: <input type="text"/>	
NPI #: <input type="text"/>			
Comments		<input type="text"/>	
Registry:		<input type="checkbox"/> No	
Registry Program Contact Name:		Phone: <input type="text"/>	
Comments		<input type="text"/>	
RETURN INSTRUCTIONS			
Contact tel. # if product received damaged:		1-866-827-3647	
Is product returnable for credit:		<input type="checkbox"/> Yes	
URL/Link to returns policy:		<input type="text"/>	
		contact - customerservice@camberpharma.com	
Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No			
If so, which states? Other requirements? Comments? <input type="text"/>			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			
<input type="text"/>			



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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>Purchase order daily receipt cut off time by supplier</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>Expedited Freight Charges or Other Designated Drop Ship Fees:</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>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <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>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: 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>Class of Trade Restriction:</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>Other Data Information Required to Process PO:</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>Return Instructions</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>Miscellaneous Notes:</p> <p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>