



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

Version 2024

Introduction Type: ☒ Final VersionDate: **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 600 mg		
Selling Unit NDC:	31722-430-60	Unit of Use NDC:	31722-430-60
UDI		CVX Code:	
		UPC:	331722430609
		MVX Code:	
Description:	Eslicarbazepine Acetate Tablets 600 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		

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?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION

The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
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:	
Is the Product... Direct-Ship Only	Unit of Use
Is the Product... Orphan Drug Status	
FDA Approval Status	
Allergens Present	Alcohol
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	60 ct
Strength:	600 mg
Dosage Form:	Tablet
Product Shape:	Oblong, with functional scoring on both sides
Product Color:	White to off-white
Product Imprint:	Engraved with 'E33' on one side and 'H' on the other side

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?:	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?	No
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/exemption/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
☒ Item/Each	N	1		00331722430609	00331722430609
☒ Box/ Carton/ Bundle/ Inner Pack					
☒ Case	N	24		20331722430603	
☐ Pallet					

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
☒ Bottle	1 Bottle of 60 Tablets
☐ Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
☐ Ampule	
☐ Glass	
☐ Tube	
☐ Vial Liquid Sgl	
☐ Vial Liquid Multi	
☐ Vial Powder Sgl	
☐ Vial Powder Multi	
☐ 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:
1 Vial	Each
(Write-in, e.g. 1 Vial)	Gram
HCPCS J-Code:	Milliliter

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.07	1.87	1.87	3.25	11.36	1
Case:	1.98	11.5	7.9	4.5	408.83	24
Pallet:						

COST INFORMATION

Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$436.39	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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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?	☐ 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	☐ 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?		☐ Yes	
If yes, indicate which:		Group 2 items (non-antineoplastic that meets a hazard criterion)	
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	
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:			



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