



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

Version 2024

Introduction Type: New Item

Final Version

Date: 7/17/2024

PRODUCT INFORMATION

Company Name: Camber Pharmaceuticals, Inc. **Application:** ANDA

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215527

Medical Device Class, if applicable:

DUNS: 11-856-3719

Proprietary Name (If Applicable) and Established Name: Divalproex Sodium Extended-Release Tablets, USP 250 mg

Selling Unit NDC: 31722-021-05 **Unit of Use NDC:** **UPC:** 331722021050

UDI **CVX Code:** **MXV Code:**

Description: Divalproex Sodium Extended-Release Tablets, USP 250 mg

Active Ingredient(s): Divalproex sodium, USP

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: Antiepileptic

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

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? 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: Months

Initial shelf life at launch (if different): 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

correctional institution block? No

opioid? No

Cannabinoid? No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

Is the Product... Direct-Ship Only Neither

Is the Product... Orphan Drug Status

FDA Approval Status

Allergens Present Soy

Country of Origin India

Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 500 ct

Strength: 250 mg

Dosage Form: Extended-release, film-coated tablet

Product Shape: Oval

Product Color: White to off white

Product Imprint: Imprinted with 'V 23' on one side and plain on

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 500 Tablets

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

Each

Inner/Carton/Pack

Case

FOR GENERIC DRUG PRODUCTS

Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB

II. Generic Equivalent to What Brand?: Depakote ER

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

HCPCS J-Code:

Rx billing unit to pharmacy:

Each

Gram

Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes

Is product exempt from DSCSA? No

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: 0331722498975

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:	0.91	3.38	3.38	6	68.55	1
Box/Carton/Bundle/Inner Pack:						
Case:	11.9	14.25	11.25	8	1282.50	12
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		00331722021050	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack					
<input checked="" type="checkbox"/> Case	N	12		20331722021054	
<input type="checkbox"/> Pallet					

COST INFORMATION

Regular Invoice Cost (WAC) (\$) \$129.50

As of date: 5/17/2024

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

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
- 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 by State(s)? No
- ARCOS Reportable? No
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II) No
- If yes, indicate which:
- 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
 - Inorganic
 - Steroid/Androgen
 - Corrosive
 - Oxidizer
 - 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:**
- 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:**
- 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:

