

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

Version 2024						Introduction Type:	New Item		x Final Version			Date:	7/17	7/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application:	ANDA	a. Temperatu	re - Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN	IDA/BLA (drug); PI	MA/510(k)(med de	vice):	21	15527				Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	ame: Diva	alproex Sodium Extended-Rele	ase Tablets, U	SP 250 mg				(write in)					
Selling Unit NDC:	31722-021-05		Unit of Use NDC:				722021050		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Description: Divalproex Sodium Extended-Release Tablets, USP 250 mg Is this product to be shipped to customers on ice? No								1					
									Is this product to be shippe				No	1
Active Ingredient(s):		Divalproex sodiu	m, USP											
								b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberphar	rma.com		_			4	Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1			State:	Address 2: NJ Zi	00054	-	Number:		732-529-042			
City:	Piscataway Customer Service	•			Email:	customerservice@car	08854	-	Group E-mail:		somaraju@r	neterousa.cor	<u>n</u>	
Key Contact: Phone Number:	1-866-827-3647	е			Fax:	732-562-8788	iberphama.com	o Special res	ulations for product in any	ctotoc?			No	7
Product Therapeutic Classification		Antiepileptic			I ax.	132-302-0100		c. Special reg					No	-
Product Therapeutic Classification	on:	Antieplieplic							Special returns requiremen	is for this product?			INO	_
	ADDIT	IONAL PRODUCT	INFORMATION			PPODLICT DESC	CRIPTION INFORMATION	d Store prod	uct (unit of sale) upright?				No	٦
	ADDITI	IONALTRODUCT		Discoul Ohio	0	T KODOCT DESC	INTERIOR IN ORMATION	u. Store prou						4
The product is?			Is the Product	Direct-Ship	Only		=00 ·		Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	500 ct	e. Shelf life:					24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				250 mg		Initial shelf life at launch (	if different):				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:	250 mg			ORDER INFORM	MATION			
component parts			T DA Approvai Giatus				Extended-release, film-			011.D211.1111.011.11				
reverse numbered?		No				Dosage Form:	coated tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 5			
latex-free?		Yes		Soy		Product Shape:	Oval		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	,	soy		Product Snape:			Ampule					
correctional institution block?		No				Product Color:	White to off white		Glass		Minimum o	der quantity	?	Yes
opioid?		No				rioduct color.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Imprinted with 'V 23' on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for						one side and plain on		Vial Liquid Multi				ch package	type?
hospital scanning?			Is this product covered to		NI.				Vial Powder Sgl		12	Each	/DI	
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)?	No				Vial Powder Multi Other: Write In			Inner/Cartor Case	/Раск	
			FOR GENERIC DRUG PR	ODUCTE					Other, write in			Case		
			FOR GENERIC DRUG PR	ODUCIS										
					Δι	thorized Generic *If A	Authorized Generic, other		PI	IARMACY ORDER	/ BILL UNIT			
	AB				710		tion fields are not applicable	Rec. sell unit						
I. Orange Book Rating:		Depakote ER						Rec. sell unit	to customer?		Rx billing u		acy:	
II. Generic Equivalent to What Bra	and?:	Deparote ER						(Write-in, e.g.	1 Vial)			Each Gram		
		DRUG SUP	PLY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION			HCPCS J-Cod				Milliliter		
				, ,										
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes		GLN:	0331722498975			ITEN	AND PACKING I	NFORMATIO	V		
Is product exempt from DSCSA?			No											
If ves. select exemption:					GCP:					Dimensi	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:								_	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product		Item/Each:	0.91	3.38	3.38	6	68.55	1
Is product sold by manufacturer's	s exclusive distrib	utor?	Yes			irect from mfr?				3.36	3.36	0	00.55	'
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer for rep	ackaged product	Box/Carton/B	undle/					
If yes, attach documentation fro	m FDA.							Inner Pack:						
								Case:	11.9	14.25	11.25	8	1282.50	12
Saleable Unit of Measure	DEID : 0/00		TIN AND HIBCC PRODUCT I	NFORMATION		N. 44								
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GII	N-14	Unit of Use GTIN-14	Pallet:						1
X Item/Each	N	Quantity 1			003	31722021050								
Box/Carton/Bundle/Inner Pack	- 14	'			- 003	31722021030			COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case	N	12			203	31722021054								
Pallet								Regular			Vendor #:			
								Invoice Cost	(WAC) (\$)	\$129.50	Whsl. Code	#:		
											Fineline Co			
								As of date:	5/17/2024		Į.			
<del>                                     </del>								Щ			<u> </u>			
1			Attach copy of SAFETY D	ATA SHEET (S	DS) or non haza		ERT, LABEL AND PHOTO OF	PRODUCT PACK						
*Please provide any additional in							gnated Drop Ship Only.		Signature:					



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#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	AZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  Does the product label bear a CA Prop 65 warning?  No	x     Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard					
c. Contact Hazard?  d. Does this product require special clean-up instructions?  (If yes, attach SDS with special instructions.)  e. Does the product contain DEHP?  No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:					
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	Is the product a NIOSH hazardous drug?  If yes, indicate which:  Group 2 items (non-antineoplastic that meets a hazard criterion)					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS					
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:					
Is the product restricted for air shipment? If so, indicate restriction:  Passenger  Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
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)	REMS:  REMS Program Manager Name:  Supplier Manages REMS registry exclusively:  Wholesale distributor support:  Provider Name:  Site Enrollment Number assigned by Supplier:  No  Phone:  DEA #:  NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP#	Registry: No Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION Is the Product	Comments					
Controlled Substance? Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No.  No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged:  Is product returnable for credit:  RETURN INSTRUCTIONS  1-866-827-3647  Yes					
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Post interest of the select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments)  Comments:	If so, which states? Other requirements? Comments?					
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:					



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#### Version 2024

#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:		Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?