

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

Version 2021 Introduction Type: New Item							x	Final Version			Date:	6/30/	2022			
PRODUCT INFORMATION								SPECIAL HANDLING AND STORAGE REQUIREMENTS*								
Company Name: Camber Pharmaceuticals, Inc. ANDA a.								a. Temperature – In	a. Temperature – Indicate the USP temperature range for this product.							
	Application Number for NDA/ADD/BLA (drug); PMA/510(k/(med device): 207961															
Medical Device Class, if applicat											0					
DUNS:	82-677-4775									Other	Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame:	Dabigatra	n Etexilate Capsules 150	mg 60ct						(write in)					
Selling Unit NDC:	31722-622-60			Unit of Use NDC:			UPC:	331722	2622608	Notes	;					
UDI				CVX Code:			MVX Code:									
								product to be shipped	to customers on i	ce?		No				
	white to yellowish									Is this	product to be shipped	to customers on o	Iry ice?		No	
Active Ingredient(s):																
URL for Additional Product Information: b. Contact for temperature excursion questions: Name: Soma Raju																
Address:						Address 2:			Number: 732-529-0423							
City:						State:	NJ	NJ Zip: 08854			Group E-mail: somaraju@heterousa.com				a.com	
Key Contact:	Customer Service					Email:	customerservi	ice@cai	mberpharma.com							
Phone Number:	1-866-827-3647	547			Fax:	732-562-8788	-562-8788		c. Special regulations for product in any states? No Special returns requirements for this product? No							
Product Therapeutic Classification	n:	Direct Thrombin Inhibitor														
	ADDITIC	ONAL PRODU					PRODUCT	DESCRIF	PTION INFORMATION	d. Store product (ur					No	
The product is?				Is the Product	Direct-Ship C	nly		-			ct product (unit of s	ale) from light?			No	
a legend device?		No		Is the Product	Unit of Use		Size:	6	60ct	e. Shelf life:					24	Months
if yes, enter class # a product kit?		NI-		Orphan Drug Status				_	150mg	Initia	l shelf life at launch (if different):				Months
if yes, list NDCs of		No		FDA Approval Status			Strength:		Toumg			ORDER INFORM				
component parts			ſ	T DA Approvar Status					Oral Solid - Capsule			ORBER IN OR				
reverse numbered?		No	L				Dosage For	m:	orar ound ouppard	Unit	of Sale		What is the	NDC selling	unit?	
co-licensed?		No		Allergens Present						x	Bottle		1 bottle of 60) capsules	·	
latex-free?		Yes	[Product Sha	ane [.]	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes					i roudet one	· .			Ampule					
correctional institution block?		No					Product Col		Cream opaque cap and		Glass		Minimum or	rder quantity	y?	Yes
opioid? Cannabinoid?		No		Country of Origin	India				Body 'H' on cap and 'D11' on		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for	No		Country of Origin	India		Product Imp		body		Vial Liquid Sgl		If Yes, how	many of wh	ich nackage	type?
hospital scanning?				Is this product covered un	nder the			6	,		Vial Powder Sql			Each	ion puonago	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
If Unit Dose, indicate NDC here:				Trade Agreements Act (T		No					Vial Power Multi			Inner/Cartor	/Pack	
											Other: Write In		1	Case		
			FO	OR GENERIC DRUG PRO	DUCTS											
									PHARMACY ORDER / BILL UNIT							
					_	AL	thorized Generic		norized Generic, other I fields are not applicable			ARMAGTORDER				
	AB	Dradava						5000011		Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Pradaxa									(Write-in, e.g. 1 Vial) Each							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(write-iii, e.g. i viai				Milliliter				
					,											
Does supplier meet DSCSA defini	tion of manufactu	irer?		Yes		GLN:	0331722000000				ITEM	AND PACKING IN	FORMATION			
Is product exempt from DSCSA?				No												
If yes, select exemption:						GCP:					Weight Lbs.		ons (US msm		Volume	Saleable #
Other exemption - Write in:				N								Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	avaluative dist-th-			No Yes			riginal product irect from mfr?			Item/Each:	0.2		2.25	4		1
Is product sold by manufacturer's Has FDA granted waiver/exception				No		•	rce manufacturer f	for renac	kaged product	Box/Carton/Bundle/						
If yes, attach documentation from				110	_	FIOVICE SOUL	ce manufacturer r	orrepac	Rageu product	Inner Pack:						
										Case:	5.7	15	11	5.5		24
			GTIN AN	ND HIBCC PRODUCT IN	FORMATION						5.7	15		5.5		24
										Pallet:						
Saleable Unit of Measure	S	Saleable Quant	ity	HIBCC			N-14 31722622608		Unit of Use GTIN-14 20331722622602	└────						
X Item/Each Box/Carton/Bundle/Inner Pack		1	ŀ			003	31722022008	-	20331722022002		OST INFORMATION			VHOLESAL	ER USE ONL	v.
X Case		24	-			203	31722622602							THOLEGAL		
Pallet			-			200	0			Regular Cost			Vendor #:			
	Ι		ŀ							Invoice Cost (WAC)	(\$)	\$428.50	Whsl. Code	#:		
	Į		[Fineline Co	de:		
	-							-		As of date:						_
	1		ļ													
<u> </u>			A 44) or non her-	d lattar BACKACE						I			
*Please provide any additional inf	ormation on race		Atta	ach copy of SAFETY DAT	A SHEET (SDS) or non naza			I, LABEL AND PHOTO OF I nated Drop Ship Only.		and BARCODE.					
Flease provide any additional inf	ormation on page	· 2 .					See new p. 3 for	i Design	ated brop Ship Only.	Signa	nure:					

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

Version 2021 For Desig	nated Drop Ship Only Products, Please Use Page 3						
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? No a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No Is the product a CA Prop 65 carcinogen? No Does 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? No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	x 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: Image: Contact Hazard						
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	Is the product a NIOSH hazardous drug? No If yes, indicate which: Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard? No							
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	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 No Limited Distribution Requirement Image: 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? (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);	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: DEA #: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:						
SP#	Registry: No						
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name: Phone: Comments						
No Controlled Substance? Controlled Substance? No Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?: No	Contact tel, # if product received damaged: 1-866-827-3647						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
Comments:							
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:						



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

Version 2021 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 Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
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:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?