

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

Version 2020				Introduction Type:	Post Launch Change		x Final Version			Date:	9/6/	/2022
		PRODUCT INFORMATION					SPECIAL HAN	IDLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	ANDA	a. Temperature – I	ndicate the USP temp	erature range for	this product.							
	Viona Pharmaceuticals Inc. NDA/BLA (drug); PMA/510(k)(med d	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)										
DUNS:	081468959	·				•	er Temperature Range	Requirement				
Proprietary Name (If Applicable)		pamate Tablets, USP 400 mg				1	(write in)	. toquii oiii oiit				
Selling Unit NDC:	72578-056-01	Unit of Use NDC:		UPC: 372578	056018	Not						
UDI	N/A	CVX Code:		MVX Code: N/A								
Description:	Off-white to pale yellow colored, car	psule shaped biconvex tablets, debossed with	n "10" and "53" s	eparated by breakline on o	one side and plain on other.	Is th	nis product to be shippe	d to customers on i	ice?		No	
					Ť	Is th	nis product to be shippe	d to customers on	dry ice?		No	_
Active Ingredient(s):	Felbamate, USF											
							perature excursion qu	estions:				
URL for Additional Product Inform Address:	mation: www.vionaus 20 Commerce Drive	sa.com		Address 2: Suite 3	40	Nar			Customer S 888-304-502			
City:	Cranford		State:	Address 2: Suite 3 NJ Zip:			nber: oup E-mail:				onausa.com	
Key Contact:	Chris Urbanski		Email:	Curbanski@vionausa			up L-man.		customers	el vice w vic	Ullausa.cull	
Phone Number:	908-956-0600		Fax:	908-514-4005	n.com	c. Special regulati	ons for product in any	states?			No	
Product Therapeutic Classification		ticonvulsant					cial returns requiremen				No	-
												_
	ADDITIONAL PRODUCT	INFORMATION		PRODUCT DESCR	IPTION INFORMATION	d. Store product (unit of sale) upright?				No	
The product is?		Is the Product Direct-Ship	Only			Pro	tect product (unit of s	ale) from light?			No	=
a legend device?	No	Is the Product Neither	,	Size:	100 ct	e. Shelf life:		,g			24	Months
if yes, enter class #		Orphan Drug Status		Size:	100 Ct	Init	ial shelf life at launch	(if different):				Months
a product kit?	No			Strength:	400 mg							_
if yes, list NDCs of		FDA Approval Status		J				ORDER INFOR	MATION			
component parts reverse numbered?	Ne			Dosage Form:	Tablets		t of Sale		What is the	NDC selling	a unit?	
co-licensed?	No No	Allergens Present					x Bottle		1 Bottle of 1		y unit:	
latex-free?	Yes	7.110. 90110 1 1000111			0 1		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?	Yes			Product Shape:	Capsule		Ampule			•	*	
correctional institution block?	No			Product Color:	Off-white to pale yellow		Glass		Minimum o	rder quantit	y?	Yes
opioid?	No			Troduct Golor.	On-write to pale yellow		Tube					
Cannabinoid?	No	Country of Origin India		Product Imprint:	"10" ; "53"		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for hospital	to this and death account on the the		1		-	Vial Liquid Multi				ich package	type?
scanning? If Unit Dose, indicate NDC here:		Is this product covered under the Trade Agreements Act (TAA)?	No			 	Vial Powder Sql Vial Power Multi		15	Each Inner/Cartor	n/Pook	
ii Oliii Dose, ilidicate NDC fiere.		Trade Agreements Net (1704):	140				Other: Write In		1	Case	II/I duk	
		FOR GENERIC DRUG PRODUCTS				<u></u>						
			Autho	orized Generic *If Auth	orized Generic, other section		Pl	ARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB		· <u> </u>	fields a	re not applicable	Rec. sell unit to co	ustomer?		Rx billing u	nit to pharm	nacy:	
II. Generic Equivalent to What Br						1	Bottle	1	x	Each	•	
	•					(Write-in, e.g. 1 Vi	al)	-		Gram		
	DRUG SUP	PLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION							Milliliter		
Does supplier meet DSCSA defin	ition of manufacturar?	Yes G	iLN:	0372578000004			ITE	M AND PACKING I	NEOPMATIO	M		
Is product exempt from DSCSA?		No No	LIT.	0372370000004				TAND FACKING	M-OKWATIO	N-		
If yes, select exemption:						1		Dimono	ions (US msn	nto \	Volume	
Other exemption - Write in:							Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?		No If	Yes, was origin	nal product purchased		Item/Each:					(0000)	
Is product sold by manufacturer	s exclusive distributor?		irect from mfr?	p			0.2	1.88	1.88	3.43		1
Has FDA granted waiver/exception	on/exemption for product?	No If	yes, attach doo	cumentation from FDA.		Box/Carton/Bundl	e/					
						Inner Pack:						
	G	TIN AND HIBCC PRODUCT INFORMATION	l .			Case:	6.34	9.72	5.91	4.52		15
Colorable Heit of Manager		LUDGO	O.T.IV		OTN			-				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-	14 578056018	Unit of Use GTIN-14	Pallet:	902.64	47.24409	39.3701	49.21		2,100
Box/Carton/Bundle/Inner Pack			00372	07 0000010								
x Case	15 40372578056016					COST INFORMATION WHOLESALER USE ONLY:						
x Pallet	2,100											
						Regular Cost			Vendor #:			
						Invoice Cost (WA	C) (\$)		Whsl. Code			
	_		_			An of detail		J	Fineline Co	de:		
						As of date:						
		Attach copy of SAFETY DATA SHEET (S	IDS) or non haza	ard letter PACKAGE INISE	RT LAREL AND PHOTO OF	PRODUCT PACKACIA	IG and BARCODE					
*Please provide any additional in	formation on page 2.	Attach copy of SAFETY DATA SHEET (S	DS) or non haza	ard letter, PACKAGE INSE See new p. 3 for Design			NG and BARCODE.					



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

Version 2020

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ZARD 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	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? Is this product regulated for shipment by DOT?	Aerosol Class; Identify NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics REMS or REGISTRY RESTRICTIONS					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:					
e. Inhalation Hazard? 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?) No					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? 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: PROMOTION Phone: DEA #: PCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: Registry Program Contact Name: Phone:					
Is the Product Controlled Substance? No Controlled Substance Code	Comments RETURN INSTRUCTIONS					
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: Ves					
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:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?					
	OUS NOTES and/or Image of Product Barcode:					



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

Version 2020

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