

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

Version 2020				Introduction Type:	Post Launch Change)	Final Version			Date:	9/6/2	2022
		PRODUCT INFORMATION					SPECIAL HAN	IDLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	/iona Pharmaceuticals Inc. Application: ANDA				ANDA	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	NDA/BLA (drug); PMA/510(k)(med devi		Tem	perature Range	Controlled Room	– between 20	and 25 C (68	° – 77° F)				
DUNS:	081468959					Othe	r Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ate Tablets, USP 400 mg					(write in)					
Selling Unit NDC:	72578-056-16 N/A	Unit of Use NDC: CVX Code:		UPC: 372578 MVX Code: N/A	056162	Note	S					
02.		le shaped biconvex tablets, debossed with	"40" I "FO"		and a state and a late and a three	1		44	0		No	
Description:	On-write to pale yellow colored, capsu	ie snaped biconvex tablets, debossed with	TO and 53	separated by breakline on c	one side and plain on other.		s product to be shipped s product to be shipped				No	
Active Ingredient(s): Felbamate, USP												
	b. Contact for temperature excursion questions:											
URL for Additional Product Inforn Address:	rmation: www.vionausa.com 20 Commerce Drive			Address 2: Suite 340			Name: Number:			Customer Service 888-304-5022		
City:	Cranford			State: NJ Zip: 07016		Group E-mail:			customerservice@vionausa.com			
Key Contact:	Chris Urbanski				a.com	1			dustomerser viace viandasarcom			
Phone Number:	908-956-0600		Fax:	908-514-4005		c. Special regulation	ns for product in any	states?			No	•
Product Therapeutic Classification	Antiepileptic/Anticor	nvulsant				Spec	ial returns requiremen	ts for this product?			No	-
	ADDITIONAL PRODUCT INF	CORMATION		PRODUCT DESCR	IPTION INFORMATION		nit of sale) upright?				No	
	ADDITIONAL PRODUCT INF			PRODUCT DESCR	IPTION INFORMATION	11						
The product is? a legend device?	No	Is the Product Direct-Ship (Jnly			e. Shelf life:	ect product (unit of s	ale) from light?			No 24	Months
if yes, enter class #	140	Orphan Drug Status		Size:	90 ct		ıl shelf life at launch ((if different):				Months
a product kit?	No			Strength:	400 mg							1
if yes, list NDCs of		FDA Approval Status		oog	100 mg			ORDER INFORI	MATION			
component parts reverse numbered?	No			Dosage Form:	Tablets	Unit	of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present							1 Bottle of 90			
latex-free?	Yes	_		Product Shape:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?	Yes			i roduct onapc.	Опроинс		Ampule				_	
correctional institution block? opioid?	No No			Product Color:	Off-white to pale yellow		Glass Tube		Minimum o	rder quantity	1?	Yes
Cannabinoid?	No	Country of Origin India					Vial Liquid Sgl					
If Unit Dose, is item bar coded to u				Product Imprint:	"10" ; "53"		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
scanning?		Is this product covered under the					Vial Powder Sql		15	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	No				Vial Power Multi Other: Write In		1	Inner/Carton Case	/Pack	
<u> </u>		FOR GENERIC DRUG PRODUCTS					Carer: Write in		<u> </u>	Odsc		
			Auth		orized Generic, other section		Pŀ	HARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:					re not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Bra	and?: Felbatol						Bottle	1	X	Each		
	DRUG SUPPLY	Y CHAIN SECURITY ACT (DSCSA) INFO	RMATION			(Write-in, e.g. 1 Via)			Gram Milliliter		
Does supplier meet DSCSA defini	ition of manufacturer?	Yes GL No	_N:	0372578000004			ITEN	M AND PACKING I	NFORMATION	1		
Is product exempt from DSCSA?		NO						D !	(110			
If yes, select exemption: Other exemption - Write in:							Weight Lbs.	Dimens	ions (US msn Width	its.) Height	Volume (Cube)	# Pieces:
Is product repackaged?		No If '	Yes, was origi	nal product purchased		Item/Each:	0.477	1.88		_	(0000)	4
Is product sold by manufacturer's			rect from mfr				0.177	1.00	1.88	3.43		1
Has FDA granted waiver/exception	on/exemption for product?	No If y	yes, attach do	cumentation from FDA.		Box/Carton/Bundle Inner Pack:	1					
	GTIN	I AND HIBCC PRODUCT INFORMATION				Case:						
						Just.	5.73	9.72	5.91	4.52		15
Saleable Unit of Measure	Quantity	HIBCC	GTIN		Unit of Use GTIN-14	Pallet:	816.29	47.24409	39.3701	49.21		2,100
X Item/Each	1		00372	2578056162			,					,
Box/Carton/Bundle/Inner Pack X Case	er Pack 40372578056160						COST INFORMATION WHOLESALER USE ONLY:				.Y:	
x Pallet	2,100			2578056167								
						Regular Cost			Vendor #:			
	-		-			Invoice Cost (WAC) (\$)		Whsl. Code Fineline Co			
	1					As of date:		1	- memie co	uc.		
			_									
*Please provide any additional inf		Attach copy of SAFETY DATA SHEET (SE	OS) or non haz	ard letter, PACKAGE INSE See new p. 3 for Design			G and BARCODE. ature:					



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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:					



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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:	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?					
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