

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

Version 2020						Introduction Type:	New Item] [x Final Version			Date:	7/6/	2023
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Viona Pharmaceuticals Inc. Application: ANDA					ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/Al	IDA/BLA (drug); PMA/510(k)(med device): 21747				471			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS:	081468959							_	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable)		: Lopera	amide Hydrochloride Capsule	s, USP 2 mg	•]	(write in)					
Selling Unit NDC:	72578-138-05		Unit of Use NDC:			UPC: 372578	138059	'	Notes					
52.	N/A		CVX Code:			MVX Code: N/A								
Description:	White to off-white col black ink.	ored granular pov	wder filled in size '3' hard gel	atin capsule wit	h cream opaq	ue cap and cream opaque l	body printed with 1701 in		s this product to be shipped s this product to be shipped				No No	
Active Ingredient(s):		peramide Hydro	chloride, USP					i l '	s triis product to be sriippet	to customers on	ury ice:		INU	-
									b. Contact for temperature excursion questions:					
URL for Additional Product Infor		ww.vionausa.	<u>com</u>					4	Name:		Customer S			
Address:	20 Commerce Drive			Address 2: Suite 340			Number: Group E-mail:			888-304-5022 customerservice@vionausa.com				
City: Key Contact:	Cranford Chris Urbanski			Email:	Curbanski@vionausa		 '	Group E-mail:		customers	service@vic	nausa.com		
Phone Number:	908-956-0600				Fax: 908-514-4005			c. Special regulations for product in any states?					No	
Product Therapeutic Classification	on: Ai	nti-Diarrheal							Special returns requirement				No	-
					1					·				•
	ADDITIONA	L PRODUCT IN	FORMATION			PRODUCT DESCR	IPTION INFORMATION	d. Store produc	ct (unit of sale) upright?				Yes	_
The product is?			Is the Product	Direct-Ship C	nly				Protect product (unit of sa	ale) from light?			Yes	
a legend device?	N	0	Is the Product	Neither		Size:	500 ct	e. Shelf life:					24	Months
if yes, enter class # a product kit?	N	2	Orphan Drug Status					'	nitial shelf life at launch (if different):				Months
if yes, list NDCs of	140		FDA Approval Status			Strength:	2 mg			ORDER INFOR	MATION			
component parts						Dosage Form:	Capsule							
reverse numbered?	N					Dosage Form.	Oapoulo	<u> </u>	Jnit of Sale			NDC selling	unit?	
co-licensed? latex-free?	N		Allergens Present					II - F	x Bottle Box/Carton		1 Bottle of 5	00 Capsules .g. 1 Box of 1	O Miele)	
preservative-free?	Ye Ye					Product Shape:	Capsule	II F	Ampule		(vviite-iii, e	.g. i bux ui ii	J Viais)	
correctional institution block?						Product Color:	Cream opaque cap &	II F	Glass		Minimum o	rder quantity	/?	Yes
opioid?	Ne	0				Product Color:	Cream opaque body		Tube					
Cannabinoid?	<u>N</u>	0	Country of Origin	India		Product Imprint:	"1701"	II	Vial Liquid Sgl					
If Unit Dose, is item bar coded to scanning?	unit dose for hospital		Is this product covered u	adar tha		•		II F	Vial Liquid Multi Vial Powder Sql		If Yes, how	many of whi Each	ch package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No			II F	Vial Powder Sqi Vial Power Multi		12	Inner/Carton	/Pack	
				,				II F	Other: Write In		1	Case		
			FOR GENERIC DRUG PR	ODUCTS				_				_		
	Authorized Generic *If Authorized Generic, other section fields are not applicable													
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Imodium				lieius ai	Rec. sell unit to customer?			7	Rx billing unit to pharmacy:					
II. Generic Equivalent to what Br	rand?:	noaium						(Write-in, e.g. 1		1	x	Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION			(vviite iii, e.g. i	vicij			Milliliter		
												•		
Does supplier meet DSCSA defin Is product exempt from DSCSA?		?	Yes No	GL	N:	0372578000004			ITEN	I AND PACKING	INFORMATIO	N		
If yes, select exemption:	_		140	_				4		Dimono	ions (US msn	nto \	Volume	
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?	_		No	If Y	es, was origi	nal product purchased		Item/Each:	0.07	2.64	2.64	4.97		1
Is product sold by manufacturer			No	_	ect from mfr?					2.04	2.04	4.97		'
Has FDA granted waiver/exception	on/exemption for prod	uct?	No	If y	es, attach do	cumentation from FDA.		Box/Carton/Bu Inner Pack:	ndle/					
		GTI	N AND HIBCC PRODUCT IF	NEORMATION				Case:						
								Case.	7.48	11.3	7.51	4.33		12
Saleable Unit of Measure	Q	uantity	HIBCC		GTIN-		Unit of Use GTIN-14	Pallet:	780.62	47.24	39.37	49.21		1,224
X Item/Each		1			00372	2578138059			700.02		00.07	10.21		1,221
Box/Carton/Bundle/Inner Pack X Case	<u> </u>	12			40373	2578138057			COST INFORMATION			WHOLESAL	FR USE ONL	γ
X Case Pallet		1,224				2578138054			JOOT INFORMATION			MOLLOAL	LIT OOL ONL	
		,						Regular Cost			Vendor #:			
								Invoice Cost (V	VAC) (\$)		Whsl. Code			
								As of data:		L	Fineline Co	de:		
					J <u> </u>			As of date:			-			
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haz	ard letter, PACKAGE INSE	RT, LABEL AND PHOTO OF	PRODUCT PACKA	GING and BARCODE.					
*Please provide any additional in	formation on page 2.			- (See new p. 3 for Design			Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	AZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No 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? No	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 c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	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	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:						
d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: PDEA #: PCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION Is the Product	Comments						
Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: Www.vionausa.com						
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?						
MISCELLAI	IEOUS 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: Monday
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:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?
	Is product order for restocking purposes?