

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

Version 2020						Introduction Type:	New Item	] [	x Final Version			Date:	7/14	/2022
			PRODUCT INFORMAT	ΓΙΟΝ					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Viona Pharmaceuticals Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k)(med device):				9966			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS:	081468959							C	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		: Modaf	nil Tablets, USP 100 mg					]	(write in)					
Selling Unit NDC:	72578-005-16		Unit of Use NDC:			UPC: 3725780	005160	, n	lotes					
02.	N/A		CVX Code:			MVX Code: N/A		!						
Description:	White to off-white, ca	psule shaped un	coated tablets, debossed wit	h "1072" on one	side and plain	on the other side			s this product to be shipped s this product to be shipped				No No	-
Active Ingredient(s):   Modafinil, USP									s triis product to be sriippet	i to customers on t	uly ice :		INU	-
								b. Contact for temperature excursion questions:						
URL for Additional Product Inform		ww.vionausa.	<u>com</u>			Address 2: Suite 3		4 1	lame:		Customer S 888-304-502			
Address: City:	20 Commerce Drive Cranford			Address 2: Suite 340 State: NJ Zip: 07016			Number: Group E-mail:			customerservice@vionausa.com				
Key Contact:	Cranford Chris Urbanski			Email:	Curbanski@vionausa		1	Group E-mail.			customerservice@vionausa.com			
Phone Number:	908-956-0600				Fax: 908-514-4005			c. Special regulations for product in any states?			No			
Product Therapeutic Classificatio	on: W	akefulness prom	oting agent					S	Special returns requirement	s for this product?			No	-
					•			.						-
	ADDITIONA	L PRODUCT IN				PRODUCT DESCR	IPTION INFORMATION	1	t (unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship O	nly				Protect product (unit of sa	ale) from light?			No	1
a legend device? if yes, enter class #	N	0	Is the Product Orphan Drug Status	Neither		Size:	90ct	e. Shelf life:	nitial shelf life at launch (	if different):			24	Months Months
a product kit?	N	0	Orphan Drug Status				400	"	illiai sileli ille at laulicii (	ii dinerentj.				Months
if yes, list NDCs of			FDA Approval Status			Strength:	100 mg			ORDER INFOR	MATION			
component parts						Dosage Form:	Uncoated Tablet							
reverse numbered? co-licensed?	No.		Allergens Present					-	Init of Sale x Bottle		1 Bottle of 9	NDC selling	unit?	
latex-free?	Ye		Allergens Fresent						Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?	Ye					Product Shape:	Capsule		Ampule		(	.g		
correctional institution block?	Ye				•	Product Color:	White to off-white		Glass		Minimum o	rder quantity	/?	Yes
opioid?	No		0				TTIMO TO OIL WING		Tube					
Cannabinoid?  If Unit Dose, is item bar coded to u	Nit dose for beenital	0	Country of Origin	Italy		Product Imprint:	"1072"		Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	oh naakaaa	tuno?
scanning?	unit dose for nospital		Is this product covered up	nder the					Vial Powder Sql		24	TEach	cn package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		Yes				Vial Power Multi			Inner/Cartor	/Pack	
			_					]  [	Other: Write In		1	Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Auth	orized Conorio *If Author	orized Conorio other coetion		PH	ARMACY ORDER	R/BILL LINIT			
I Orange Book Pating	Authorized Generic *If Authorized Generic, other section fields are not applicable							Rec. sell unit to customer? Rx billing unit to pharmacy:						
I. Orange Book Rating:  II. Generic Equivalent to What Brand?:  Provigil							1 Bottle			x Each				
	<u>.                                    </u>							(Write-in, e.g. 1	Vial)	+		Gram		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Milliliter														
Does supplier meet DSCSA defini	ition of manufacturer	2	Yes	GL	N-	0372578000004		1	ITEN	AND PACKING I	INFORMATIO	N		
Is product exempt from DSCSA?			No	_		00/20/000001								
If yes, select exemption:				<u> </u>		-		1		Dimens	ions (US msr	nts.)	Volume	
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?			No			nal product purchased		Item/Each:	0.11	1.61	1.61	2.98		1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			No No	_	ect from mfr?	cumentation from FDA.		Box/Carton/Bur	adla/					
has FDA granted warver/exceptio	in/exemption for prod	uct:	140	" y	es, allacii uo	cumentation from FDA.		Inner Pack:	iule/					
		GTI	N AND HIBCC PRODUCT IN	NFORMATION				Case:	3.81	9.72	6.49	3.81		24
									3.01	9.12	0.43	3.01		24
Saleable Unit of Measure  x Item/Each	Q	uantity 1	HIBCC		GTIN-	14 578005160	Unit of Use GTIN-14	Pallet:	772.81	47.24	39.37	47.24		4,752
X Item/Each Box/Carton/Bundle/Inner Pack		'			00372	370003100								
X Case		24				578005168			COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
x Pallet	_	4,752				578005165								
								Regular Cost	(AC) (6)		Vendor #:	м.		
								Invoice Cost (W	(a) (a)		Whsl. Code			
	7 H							As of date:			7			
						•								
*Please provide any additional inf	formation on none 2		Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE INSER	RT, LABEL AND PHOTO OF		GING and BARCODE.					



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### For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD 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: PROPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  Registry Program Contact Name:  Phone:					
ADD'L STORAGE INFORMATION  Is the Product	Comments					
Controlled Substance? Yes Controlled Substance Code I680  Controlled by State(s)? Yes Listed Chemical (List I or II) No  ARCOS Reportable? No If yes, indicate which:  Schedule No. 4 Is it a scheduled listed chemical product?: No  CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged:  Is product returnable for credit:  URL/Link to returns policy:  RETURN INSTRUCTIONS  888-304-5022  Yes					
No restriction: Select YES # 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)	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?					
Comments:  MISCELLANEC	DUS NOTES and/or Image of Product Barcode:					
MISCELLANEC	NOC NOTED distance image of 1 founds bulled up.					



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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:  a. EDI  b. Autofax  Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax Fax Number: d. Phone only e. Supplier Web Site only Site Address:	Shipping lead time of PO: Hours Days  Ships same day for next day receipt:
Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Phone:	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:	Overnight receipt available:
Drop Ship service fee billed with each order:	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, 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:	Saturday Overnight receipt available:  PO Receipt Cut off time: Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to Process 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?