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

Version 2020 | Introduction Type: New Item | x Final Version | Date: 7/14/2022

## PRODUCT INFORMATION

| | | | | | |
|---|---|---|---|---|---|
| **Company Name:** | Viona Pharmaceuticals Inc. | | | **Application:** | ANDA |
| **Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** | 209966 | | | | |
| **DUNS:** | 081468959 | | | | |
| **Proprietary Name (If Applicable) and Established Name:** | Modafinil Tablets, USP 200 mg | | | | |
| **Selling Unit NDC:** | 72578-006-06 | **Unit of Use NDC:** | | **UPC:** | 372578006068 |
| **UDI** | N/A | **CVX Code:** | | **MVX Code:** | N/A |
| **Description:** | White to off-white, capsule shaped uncoated scored tablet, debossed with "10" & "73" on either side of scoreline on one side and plain on other side. | | | | |
| **Active Ingredient(s):** | Modafinil, USP | | | | |
| **URL for Additional Product Information:** | www.vionausa.com | | | | |
| **Address:** | 20 Commerce Drive | **Address 2:** | Suite 340 | | |
| **City:** | Cranford | **State:** | NJ | **Zip:** | 07016 |
| **Key Contact:** | Chris Urbanski | **Email:** | Curbanski@vionausa.com | | |
| **Phone Number:** | 908-956-0600 | **Fax:** | 908-514-4005 | | |
| **Product Therapeutic Classification:** | Wakefulness promoting agent | | | | |

## ADDITIONAL PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| **The product is?** | | **Is the Product…** | Direct-Ship Only |
| **a legend device?** | No | **Is the Product…** | Neither |
| **if yes, enter class #** | | **Orphan Drug Status** | |
| **a product kit?** | No | | |
| **if yes, list NDCs of component parts** | | **FDA Approval Status** | |
| **reverse numbered?** | No | | |
| **co-licensed?** | No | **Allergens Present** | |
| **latex-free?** | Yes | | |
| **preservative-free?** | Yes | | |
| **correctional institution block?** | Yes | | |
| **opioid?** | No | | |
| **Cannabinoid?** | No | Country of Origin | Italy |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | | | |
| If Unit Dose, indicate NDC here: | | Is this product covered under the Trade Agreements Act (TAA)? | Yes |

## PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| **Size:** | 30ct |
| **Strength:** | 200 mg |
| **Dosage Form:** | Uncoated Tablet |
| **Product Shape:** | Capsule |
| **Product Color:** | White to off-white |
| **Product Imprint:** | "10 & 73" |

## FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:** AB

**II. Generic Equivalent to What Brand?:** Provigil

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

| | | | |
|---|---|---|---|
| **Does supplier meet DSCSA definition of manufacturer?** | Yes | **GLN:** | 0372578000004 |
| **Is product exempt from DSCSA?** | No | | |
| **If yes, select exemption:** | | | |
| **Other exemption - Write in:** | | | |
| **Is product repackaged?** | No | **If Yes, was original product purchased direct from mfr?** | |
| **Is product sold by manufacturer's exclusive distributor?** | No | | |
| **Has FDA granted waiver/exception/exemption for product?** | No | **If yes, attach documentation from FDA.** | |

## GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|
| x | Item/Each | 1 | | 00372578006068 | |
| | Box/Carton/Bundle/Inner Pack | | | | |
| x | Case | 24 | | 40372578006066 | |
| x | Pallet | 4,752 | | 50372578006063 | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

## SPECIAL HANDLING AND STORAGE REQUIREMENTS*

**a. Temperature – Indicate the USP temperature range for this product.**

Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

**b. Contact for temperature excursion questions:**

**Name:** Customer Service

**Number:** 888-304-5022

**Group E-mail:** customerservice@vionausa.com

**c. Special regulations for product in any states?** No

Special returns requirements for this product? No

**d. Store product (unit of sale) upright?** Yes

**Protect product (unit of sale) from light?** No

**e. Shelf life:** 24 Months

**Initial shelf life at launch (if different):** Months

## ORDER INFORMATION

**Unit of Sale**

| | |
|---|---|
| x | Bottle |
| | Box/Carton |
| | Ampule |
| | Glass |
| | Tube |
| | Vial Liquid Sgl |
| | Vial Liquid Multi |
| | Vial Powder Sql |
| | Vial Power Multi |
| | Other: Write In |

**What is the NDC selling unit?** 1 Bottle of 30 tablets

(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?** Yes

**If Yes, how many of which package type?**

| | |
|---|---|
| 24 | Each |
| | Inner/Carton/Pack |
| 1 | Case |

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?** 1 Bottle

(Write-in, e.g. 1 Vial)

**Rx billing unit to pharmacy:**

| | |
|---|---|
| x | Each |
| | Gram |
| | Milliliter |

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | # Pieces: |
|---|---|---|---|---|---|---|
| **Item/Each:** | 0.98 | 1.61 | 1.61 | 2.98 | | 1 |
| **Box/Carton/Bundle/ Inner Pack:** | | | | | | |
| **Case:** | 3.42 | 9.72 | 6.49 | 3.81 | | 24 |
| **Pallet:** | 695.55 | 47.24 | 39.37 | 47.24 | | 4,752 |

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) ($)**

As of date:

## WHOLESALER USE ONLY:

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

**Signature:**

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

**Version 2020**

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

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

- Is the product a CA Prop 65 carcinogen? No
- Is 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? No

Is this product regulated for shipment by DOT? No
(if yes, answer a-e below and provide SDS)

a. UN/Identification Number
b. Proper Shipping Name
c. DOT Hazard Class
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
c. DOT Hazard Class
d. Packing Group
e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ 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)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);
  SP#

### SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard

☐ Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

## REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
If Yes, is it managed with a pharmacy registry?
Website URL:

Med Guide Required No

Limited Distribution Requirement No

Comments / Details: (For example, iPledge program?)

**REMS:**

REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: PCPDP#:
NPI #:

Comments

**Registry:**

Registry Program Contact Name: Phone:
Comments

## ADD'L STORAGE INFORMATION

Is the Product…

| | | | |
|---|---|---|---|
| Controlled Substance? | Yes | Controlled Substance Code | 1680 |
| 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:

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:

## RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 888-304-5022

Is product returnable for credit: Yes

URL/Link to returns policy: www.vionausa.com

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

## MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

# 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

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:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

## Standard Order Receipt and Processing

**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:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:**
PO Receipt cut off time:
Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

**Priority Overnight receipt available:**
PO Receipt Cut off time:

**Saturday Overnight receipt available:**
PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

## 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:

## Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

## Return Instructions

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?