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

Version 2024 | Introduction Type: New Item | x Final Version | Date: 9/28/2026

## PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| Company Name: | Viona Pharmaceuticals Inc. | Application: | ANDA |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 219253 | NDA 505(b) Type: | NOT APPLICABLE |
| Medical Device Class, if applicable: | | | |
| DUNS: | 081468959 | | |
| Proprietary Name (If Applicable) and Established Name: | Diltiazem Hydrochloride Tablets, USP 120 mg | | |
| Selling Unit NDC: | 72578-202-01 | Unit of Use NDC: | UPC: 372578202019 |
| UDI | N/A | CVX Code: | MVX Code: N/A |
| Description: | White to off white colored, capsule shaped, biconvex, uncoated tablets debossed with the "18" and "70", separated with scoreline on one side and plain on another side. | | |
| Active Ingredient(s): | Diltiazem Hydrochloride, USP | | |
| URL for Additional Product Information: | www.vionausa.com | | |

| | | | |
|---|---|---|---|
| Address: | 20 Commerce Drive | Address 2: | Suite 340 |
| City: | Cranford | State: | New Jersey Zip: 07016 |
| Key Contact: | Chris Urbanski | Email: | Curbanski@vionausa.com |
| Phone Number: | 908-956-0600 | Fax: | 908-514-4005 |
| Product Therapeutic Classification: | Anti-agina | | |

## 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? | No | | |
| opioid? | No | | |
| Cannabinoid? | No | Country of Origin | India |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | | Is this product covered under the Trade Agreements Act (TAA)? | No |
| If Unit Dose, indicate NDC here: | | | |

## PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| Size: | 100 ct |
| Strength: | 120 mg |
| Dosage Form: | Tablet |
| Product Shape: | Capsule |
| Product Color: | White to off-white |
| Product Imprint: | "18" and "70" |

## 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?: | Cardizem® |

## 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: | | GCP: | 0372578 |
| 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 | Provide source manufacturer for repackaged product | |
| If yes, attach documentation from FDA. | | | |

## GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|---|
| x | Item/Each | Y | 1 | | 00372578202019 | |
| | Box/Carton/Bundle/Inner Pack | | | | | |
| x | Case | Y | 24 | | 40372578202017 | |
| x | Pallet | Y | 2,184 | | 50372578202014 | |

## 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? | Yes | |
| e. Shelf life: | 18 | Months |
| Initial shelf life at launch (if different): | | Months |

## ORDER INFORMATION

| Unit of Sale | | What is the NDC selling unit? | |
|---|---|---|---|
| x | Bottle | 1 Bottle of 100 Tablets | |
| | Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) | |
| | Ampule | | |
| | Glass | Minimum order quantity? | Yes |
| | Tube | | |
| | Vial Liquid Sgl | | |
| | Vial Liquid Multi | If Yes, how many of which package type? | |
| | Vial Powder Sgl | 24 | Each |
| | Vial Power Multi | | Inner/Carton/Pack |
| | Other: Write In | 1 | Case |

## PHARMACY ORDER / BILL UNIT

| | | | |
|---|---|---|---|
| Rec. sell unit to customer? | | Rx billing unit to pharmacy: | |
| 1 Bottle | | x | Each |
| (Write-in, e.g. 1 Vial) | | | Gram |
| HCPCS J-Code: | | | Milliliter |

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| Item/Each: | 0.25 | 2.19 | 2.19 | 3.91 | | 1 |
| Box/Carton/Bundle/ Inner Pack: | | | | | | |
| Case: | 6.81 | 13.3 | 8.7 | 4.88 | | 24 |
| Pallet: | 797.7 | 47.2 | 39.3 | 47.2 | | 2,184 |

## 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 2024**

**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? (If yes, attach SDS with special instructions.) | No |
| e. Does the product contain DEHP? | No |
| Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) | No |
| 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? (if yes, answer a-e below and provide SDS) | No |
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | No |
| Is the product restricted for air shipment? If so, indicate restriction: | No |

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Gaargo

| | |
|---|---|
| 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

| | |
|---|---|
| Does the product have an Aerosol class? If yes, identify NFPA Storage Level: | No |
| 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: | | NCPDP#: | |
| | | NPI #: | |

Comments

**Registry:**

| | | | |
|---|---|---|---|
| Registry Program Contact Name: | | Phone: | |
| Comments | | | |

## ADD'L STORAGE INFORMATION

Is the Product…

| | | | |
|---|---|---|---|
| Controlled Substance? | No | Controlled Substance Code | |
| Controlled by State(s)? | No | Listed Chemical (List I or II) | |
| ARCOS Reportable? | No | If yes, indicate which: | |
| Schedule No. | | 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 | |
| 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 2024**

**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:

## 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:

## 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:

## Miscellaneous Notes:

## 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:

## 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:

## 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?

## ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?