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

**Version 2024**

**Introduction Type:** New Item  **x** Final Version  **Date:** 12/19/2024

## PRODUCT INFORMATION

| Field | Value |
|---|---|
| Company Name: | Camber Pharmaceuticals, Inc. |
| Application: | ANDA |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 204389 |
| NDA 505(b) Type: | NOT APPLICABLE |
| Medical Device Class, if applicable: | |
| DUNS: | 11-856-3719 |
| Proprietary Name (If Applicable) and Established Name: | Memantine Hydrochloride Tablets, USP 5 mg |
| Selling Unit NDC: | 31722-807-60 |
| Unit of Use NDC: | 31722-807-60 |
| UPC: | 331722807609 |
| UDI: | |
| CVX Code: | |
| MVX Code: | |
| Description: | Memantine Hydrochloride Tablets, USP 5 mg |
| Active Ingredient(s): | Memantine hydrochloride, USP |
| URL for Additional Product Information: | www.camberpharma.com |
| Address: | 800 Centennial Ave, Suite 1 |
| Address 2: | |
| City: | Piscataway |
| State: | NJ |
| Zip: | 08854 |
| Key Contact: | Customer Service |
| Email: | customerservice@camberpharma.com |
| Phone Number: | 1-866-827-3647 |
| Fax: | 732-562-8788 |
| Product Therapeutic Classification: | N-methyl-D-aspartate (NMDA) receptor antagonist |

## ADDITIONAL PRODUCT INFORMATION

| Field | Value |
|---|---|
| The product is? | |
| a legend device? | No |
| if yes, enter class # | |
| a product kit? | No |
| if yes, list NDCs of component parts | |
| reverse numbered? | No |
| co-licensed? | No |
| latex-free? | Yes |
| preservative-free? | Yes |
| correctional institution block? | No |
| opioid? | No |
| Cannabinoid? | No |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | |
| If Unit Dose, indicate NDC here: | |

| Field | Value |
|---|---|
| Is the Product… | Direct-Ship Only |
| Is the Product… | Unit of Use |
| Orphan Drug Status | |
| FDA Approval Status | |
| Allergens Present | Dairy, Lactose, Casein, Dye, Corn, Alcohol |
| Country of Origin | India |
| Is this product covered under the Trade Agreements Act (TAA)? | No |

## PRODUCT DESCRIPTION INFORMATION

| Field | Value |
|---|---|
| Size: | 60 ct |
| Strength: | 5 mg |
| Dosage Form: | Film coated tablet |
| Product Shape: | Modified capsule, biconvex |
| Product Color: | Tan |
| Product Imprint: | Debossed with 'J' on one side & '47' on the other side |

## 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?: | Namenda |

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

| Field | Value |
|---|---|
| Does supplier meet DSCSA definition of manufacturer? | Yes |
| GLN: | 0331722498975 |
| Is product exempt from DSCSA? | No |
| If yes, select exemption: | |
| GCP: | |
| 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? | Yes |
| 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 | N | 1 | | 00331722807609 | 00331722807609 |
| | Box/Carton/Bundle/Inner Pack | | | | | |
| x | Case | N | 24 | | 20331722807603 | |
| | Pallet | | | | | |

## SPECIAL HANDLING AND STORAGE REQUIREMENTS*

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

| Field | Value |
|---|---|
| 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:**

| Field | Value |
|---|---|
| Name: | Soma Raju |
| Number: | 732-529-0423 |
| Group E-mail: | somaraju@heterousa.com |

| Field | Value |
|---|---|
| c. Special regulations for product in any states? | No |
| Special returns requirements for this product? | No |
| d. Store product (unit of sale) upright? | No |
| 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 | | What is the NDC selling unit? |
|---|---|---|
| x | Bottle | 1 Bottle of 60 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 Powder Multi | Inner/Carton/Pack |
| | Other: Write In | Case |

## PHARMACY ORDER / BILL UNIT

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

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| Item/Each: | 0.05 | 1.5 | 1.5 | 2.52 | 5.67 | 1 |
| Box/Carton/Bundle/Inner Pack: | | | | | | |
| Case: | 1.9 | 9.5 | 6.9 | 4 | 262.20 | 24 |
| Pallet: | | | | | | |

## COST INFORMATION

| Field | Value |
|---|---|
| Regular Cost | |
| Invoice Cost (WAC) ($) | $8.60 |
| As of date: | 12/1/2024 |

## WHOLESALER USE ONLY:

| Field | Value |
|---|---|
| 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)

## 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?

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: — No
- [ ] 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

| | | |
|---|---|---|
| x Organic | | Corrosive |
| Inorganic | | Oxidizer |
| Steroid/Androgen | | 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
Comments / Details: (For example, iPledge program?)

REMS: — No
- REMS Program Manager Name:    Phone:
- Supplier Manages REMS registry exclusively:
- Wholesale distributor support:
- Provider Name:    DEA #:
- Site Enrollment Number assigned    NCPDP#:
- by Supplier:    NPI #:
- Comments

Registry: — No
- 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) — No
- ARCOS Reportable? — No    If yes, indicate which:
- Schedule No.    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 — Yes

Restricted to retail pharmacy only: — No

Restricted to hospital, clinics, and physician offices only: — No

Restricted from US territories? (explain in comments) — No

Comments:

## RETURN INSTRUCTIONS

Contact tel. # if product received damaged: — 1-866-827-3647

Is product returnable for credit: — Yes

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? — No

If so, which states? Other requirements? Comments?

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

# 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:

## 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?