



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

Version 2024 Introduction Type:   Final Version Date:

| PRODUCT INFORMATION                                    |  |
|--|--|
| Company Name:  | Camber Pharmaceuticals, Inc.                                   |
| Application Number for NDA/ANDA/BLA; PMA/510(k):       | 204316   |
| Medical Device Class, if applicable:                   |  |
| DUNS:  | 11-856-3719  |
| Proprietary Name (If Applicable) and Established Name: | Quetiapine Tablets, USP 50 mg                                  |
| Selling Unit NDC:                                      | 31722-765-01   |
| Unit of Use NDC:                                       |  |
| CVX Code:  |  |
| UPC:   | 331722765015   |
| MX Code:   |  |
| Description:   | Quetiapine Tablets, USP 50 mg                                  |
| Active Ingredient(s):                                  | Quetiapine fumarate, USP                                       |
| URL for Additional Product Information:                | <a href="http://www.camberpharma.com">www.camberpharma.com</a> |
| Address:   | 800 Centennial Ave, Suite 1                                    |
| City:  | Piscataway   |
| Key Contact:   | Customer Service   |
| Phone Number:  | 1-866-827-3647   |
| Product Therapeutic Classification:                    | Atypical antipsychotic   |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS*                                   |  |
|--|--|
| <b>a. Temperature – Indicate the USP temperature range for this product.</b> |  |
| Temperature Range  | <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> |
| Other Temperature Range Requirement (write in)                               | <input type="text"/>   |
| Notes  | <input type="text"/>   |
| Is this product to be shipped to customers on ice?                           | <input type="text" value="No"/>  |
| Is this product to be shipped to customers on dry ice?                       | <input type="text" value="No"/>  |
| <b>b. Contact for temperature excursion questions:</b>                       |  |
| Name:  | <input type="text" value="Soma Raju"/>   |
| Number:  | <input type="text" value="732-529-0423"/>  |
| Group E-mail:  | <input type="text" value="somaraju@heterousa.com"/>                              |
| <b>c. Special regulations for product in any states?</b>                     |  |
| Special returns requirements for this product?                               | <input type="text" value="No"/>  |
| <b>d. Store product (unit of sale) upright?</b>                              |  |
| Protect product (unit of sale) from light?                                   | <input type="text" value="No"/>  |
| <b>e. Shelf life:</b>  |  |
| Initial shelf life at launch (if different):                                 | <input type="text" value="24"/> Months   |

| ADDITIONAL PRODUCT INFORMATION                                      |                                  | PRODUCT DESCRIPTION INFORMATION                               |   |
|---|----------------------------------|---|---|
| The product is?   |                                  | Is the Product... Direct-Ship Only                            | <input type="text" value="Neither"/>  |
| a legend device?  | <input type="text" value="No"/>  | Is the Product... Orphan Drug Status                          | <input type="text"/>  |
| if yes, enter class #   | <input type="text"/>             | FDA Approval Status   | <input type="text"/>  |
| a product kit?  | <input type="text" value="No"/>  | Allergens Present   | <input type="text" value="Dairy, Lactose, Animal Products"/>                          |
| if yes, list NDCs of component parts                                | <input type="text"/>             | Country of Origin   | <input type="text" value="India"/>  |
| reverse numbered?   | <input type="text" value="No"/>  | Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="No"/>   |
| co-licensed?  | <input type="text" value="No"/>  |   |   |
| latex-free?   | <input type="text" value="Yes"/> |   |   |
| preservative-free?  | <input type="text" value="Yes"/> |   |   |
| correctional institution block?                                     | <input type="text" value="No"/>  |   |   |
| opioid?   | <input type="text" value="No"/>  |   |   |
| Cannabinoid?  | <input type="text" value="No"/>  |   |   |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text"/>             |   |   |
| If Unit Dose, indicate NDC here:                                    | <input type="text"/>             |   |   |
|   |                                  | Size:   | <input type="text" value="100 ct"/>   |
|   |                                  | Strength:   | <input type="text" value="50 mg"/>  |
|   |                                  | Dosage Form:  | <input type="text" value="Film-coated tablet"/>                                       |
|   |                                  | Product Shape:  | <input type="text" value="Round, biconvex"/>  |
|   |                                  | Product Color:  | <input type="text" value="White"/>  |
|   |                                  | Product Imprint:  | <input type="text" value="Debossed with '47' on one side and '1' on the other side"/> |

| ORDER INFORMATION                          |   |
|--|---|
| Unit of Sale                               | What is the NDC selling unit?                                 |
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 Bottle of 100 Tablets"/>          |
| <input type="checkbox"/> Box/Carton        | <input type="text" value="Write-in, e.g. 1 Box of 10 Vials"/> |
| <input type="checkbox"/> Ampule            |   |
| <input type="checkbox"/> Glass             | Minimum order quantity? <input type="text" value="Yes"/>      |
| <input type="checkbox"/> Tube              |   |
| <input type="checkbox"/> Vial Liquid Sgl   |   |
| <input type="checkbox"/> Vial Liquid Multi | If Yes, how many of which package type?                       |
| <input type="checkbox"/> Vial Powder Sgl   | <input type="text" value="24"/> Each                          |
| <input type="checkbox"/> Vial Powder Multi | <input type="text"/>  |
| <input type="checkbox"/> Other: Write In   | <input type="text" value="Inner/Carton/Pack"/>                |
|  | <input type="text" value="Case"/>                             |

| FOR GENERIC DRUG PRODUCTS              |   |
|--|---|
| I. Orange Book Rating:                 | <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable |
| II. Generic Equivalent to What Brand?: | <input type="text" value="Seroquel"/>   |

| PHARMACY ORDER / BILL UNIT  |                                     |
|-----------------------------|-------------------------------------|
| Rec. sell unit to customer? | Rx billing unit to pharmacy:        |
| <input type="text"/>        | <input type="checkbox"/> Each       |
| (Write-in, e.g. 1 Vial)     | <input type="checkbox"/> Gram       |
| HCPCS J-Code:               | <input type="checkbox"/> Milliliter |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION       |  |
|--|--|
| Does supplier meet DSCSA definition of manufacturer?     | <input type="text" value="Yes"/>           |
| Is product exempt from DSCSA?                            | <input type="text" value="No"/>            |
| If yes, select exemption:                                | <input type="text"/>                       |
| Other exemption - Write in:                              | <input type="text"/>                       |
| Is product repackaged?                                   | <input type="text" value="No"/>            |
| Is product sold by manufacturer's exclusive distributor? | <input type="text" value="Yes"/>           |
| Has FDA granted waiver/exception/exemption for product?  | <input type="text" value="No"/>            |
| If yes, attach documentation from FDA.                   | <input type="text"/>                       |
| GLN:   | <input type="text" value="0331722498975"/> |
| GCP:   | <input type="text"/>                       |
| If yes, was original product purchased direct from mfr?  | <input type="text"/>                       |
| Provide source manufacturer for repackaged product       | <input type="text"/>                       |

| ITEM AND PACKING INFORMATION  |             |                        |       |        |               |                   |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
| Item/Each:                    | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|                               |             | Depth                  | Width | Height |               |                   |
| Box/Carton/Bundle/Inner Pack: | 0.09        | 1.55                   | 1.55  | 2.5    | 6.01          | 1                 |
| Case:                         | 2.45        | 9.75                   | 6.75  | 4      | 263.25        | 24                |
| Pallet:                       |             |                        |       |        |               |                   |

| GTIN AND HIBCC PRODUCT INFORMATION                               |               |                   |       |                |
|--|---------------|-------------------|-------|----------------|
| Saleable Unit of Measure   | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14        |
| <input checked="" type="checkbox"/> Item/Each                    | N             | 1                 |       | 00331722765015 |
| <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | N             | 24                |       | 20331722765019 |
| <input type="checkbox"/> Case                                    |               |                   |       |                |
| <input type="checkbox"/> Pallet                                  |               |                   |       |                |

| COST INFORMATION        |  | WHOLESALE USE ONLY: |                      |
|-------------------------|--|---------------------|----------------------|
| Regular Cost            | <input type="text"/>                   | Vendor #:           | <input type="text"/> |
| Invoice Cost (WAC) (\$) | <input type="text" value="\$8.21"/>    | Whsl. Code #:       | <input type="text"/> |
| As of date:             | <input type="text" value="3/18/2024"/> | Fineline Code:      | <input type="text"/> |

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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 & 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  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 by Supplier:  NCPDP#:   
 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  | Standard Order Receipt and Processing  |
|--|--|
| <p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/></li> <li>c. Fax <input type="checkbox"/></li> <li>d. Phone only <input type="checkbox"/></li> <li>e. Supplier Web Site only <input type="checkbox"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p> | <p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>   |
| Expedited Freight Charges or Other Designated Drop Ship Fees:  | Overnight and Priority Overnight PO Processing   |
| <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>  | <p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction:  |  |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>   | <p><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>   |
| Other Data Information Required to Process PO:   | Return Instructions  |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>   |  |
| Miscellaneous Notes:   | ADDITIONAL INFORMATION   |
| <p><input type="text"/></p>  | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |