



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

Version 2021 Introduction Type:  New Item  Final Version Date:  4/5/2023

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA  
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 215259  
**Medical Device Class, if applicable:**   
**DUNS:** 82-677-4775  
**Proprietary Name (If Applicable) and Established Name:** Levothyroxine Sodium Tablets USP, 112mcg  
**Selling Unit NDC:** 31722-289-10 **Unit of Use NDC:**  **UPC:** 331722289108  
**UDI**  **CVX Code:**  **MVX Code:**   
**Description:** Levothyroxine Sodium Tablets USP, 112mcg  
**Active Ingredient(s):** Levothyroxine Sodium  
**URL for Additional Product Information:** [www.camberpharma.com](http://www.camberpharma.com)  
**Address:** 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 **Address 2:**   
**City:** Piscataway **State:** NJ **Zip:** 08854  
**Key Contact:** Customer Service **Email:** [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)  
**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788  
**Product Therapeutic Classification:** Synthetic Thyroid Hormone

**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:** Soma Raju  
**Number:** 732-529-0423  
**Group E-mail:** [somaraju@heterousa.com](mailto:somaraju@heterousa.com)  
**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

| ADDITIONAL PRODUCT INFORMATION   |  | PRODUCT DESCRIPTION INFORMATION |  |
|--|--|---------------------------------|--|
| The product is a legend device? <input type="text"/> No                                  | Is the Product... Direct-Ship Only <input type="text"/>                                | Size:                           | 1000ct   |
| if yes, enter class # a product kit? <input type="text"/> No                             | Is the Product... Orphan Drug Status <input type="text"/>                              | Strength:                       | 112mcg   |
| if yes, list NDCs of component parts reverse numbered? <input type="text"/>              | FDA Approval Status <input type="text"/>   | Dosage Form:                    | Tablet   |
| co-licensed? <input type="text"/> No   | Allergens Present <input type="text"/>   | Product Shape:                  | capsule shaped, biconvex tablets                                 |
| latex-free? <input type="text"/> Yes   | Country of Origin <input type="text"/> USA   | Product Color:                  | Rose   |
| preservative-free? <input type="text"/> No   | Is this product covered under the Trade Agreements Act (TAA)? <input type="text"/> Yes | Product Imprint:                | plain on one side and debossed "score line 6" on the other side. |
| correctional institution block? <input type="text"/> No                                  |  |                                 |  |
| opioid? <input type="text"/> No  |  |                                 |  |
| Cannabinoid? <input type="text"/> 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"/>                                    |  |                                 |  |

**ORDER INFORMATION**

| Unit of Sale                               | What is the NDC selling unit?                    |
|--|--|
| <input checked="" type="checkbox"/> Bottle | 1 bottle of 1000 tablets                         |
| <input type="checkbox"/> Box/Carton        | (Write-in, e.g. 1 Box of 10 Vials)               |
| <input type="checkbox"/> Ampule            |  |
| <input type="checkbox"/> Glass             | Minimum order quantity? <input type="text"/> Yes |
| <input type="checkbox"/> Tube              |  |
| <input type="checkbox"/> Vial Liquid Sgl   |  |
| <input type="checkbox"/> Vial Liquid Multi |  |
| <input type="checkbox"/> Vial Powder Sgl   | If Yes, how many of which package type?          |
| <input type="checkbox"/> Vial Power Multi  | <input type="text"/> 24 Each                     |
| <input type="checkbox"/> Other: Write In   | <input type="text"/> Inner/ Carton/Pack          |
|  | <input type="text"/> Case                        |

**FOR GENERIC DRUG PRODUCTS**

**I. Orange Book Rating:**  AB4  Authorized Generic \*If Authorized Generic, other section fields are not applicable  
**II. Generic Equivalent to What Brand?:**  Thyro-Tab

**PHARMACY ORDER / BILL UNIT**

**Rec. sell unit to customer?**  (Write-in, e.g. 1 Vial)  
**Rx billing unit to pharmacy:**  Each  Gram  Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

**Does supplier meet DSCSA definition of manufacturer?**  Yes  
**Is product exempt from DSCSA?**  No  
**GLN:** 00331722000000  
**GCP:**   
**If yes, select exemption:**   
**Other exemption - Write in:**   
**Is product repackaged?**  No  
**Is product sold by manufacturer's exclusive distributor?**  Yes  
**Has FDA granted waiver/exception/exemption for product?**  No  
**If yes, attach documentation from FDA.**

**ITEM AND PACKING INFORMATION**

| Item/Each:                    | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
|                               |             | Depth                  | Width | Height |               |                   |
| Item/Each:                    | 0.33        | 2.25                   | 2.25  | 4.25   | 21.52         | 1                 |
| Box/Carton/Bundle/Inner Pack: |             |                        |       |        |               |                   |
| Case:                         | 8.55        | 14.5                   | 10    | 5      | 725           | 24                |
| Pallet:                       |             |                        |       |        |               |                   |

**GTIN AND HIBCC PRODUCT INFORMATION**

| Saleable Unit of Measure                              | Saleable Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
|---|-------------------|-------|----------------|---------------------|
| <input checked="" type="checkbox"/> Item/Each         | 1                 |       | 00331722289108 |                     |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |                   |       |                |                     |
| <input checked="" type="checkbox"/> Case              | 24                |       | 10331722289105 |                     |
| <input type="checkbox"/> Pallet                       |                   |       |                |                     |

**COST INFORMATION** **WHOLESALE USE ONLY:**

**Regular Cost**   
**Invoice Cost (WAC) (\$)**  \$165.11  
**As of date:**  4/5/2023  
**Vendor #:**   
**Whsl. Code #:**   
**Fineline Code:**



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

Version 2021

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)

- 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)

- 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:

- Passenger  No
- Cargo  No
- Passenger & Cargo  No

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#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes
- Controlled Substance Code
- Controlled by State(s)?  No  Yes
- Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes
- If yes, indicate which:
- Schedule No.
- Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### 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

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

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  Yes

If Yes, is it managed with a pharmacy registry? Website URL:

Med Guide Required  No  Yes

Limited Distribution Requirement  No  Yes

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

REMS:  No  Yes

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:  No  Yes

Wholesale distributor support:

Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  NCPDP#:

NPI #:

Comments

Registry:  No  Yes

Registry Program Contact Name:  Phone:

Comments

### RETURN INSTRUCTIONS

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

Is product returnable for credit:  Yes  No

URL/Link to returns policy:  contact - customerservice@camberpharma.com

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

If so, which states? Other requirements? Comments?

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

