



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 4/5/2023

## PRODUCT INFORMATION

**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, 75mcg

**Selling Unit NDC:** 31722-286-90 **Unit of Use NDC:** 31722-286-90 **UPC:** 331722286909

**UDI** **CVX Code:** **MXV Code:**

**Description:** Levothyroxine Sodium Tablets USP, 75mcg

**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

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

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

Temperature Range:

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:**  Months

Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

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?  No

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:

**Is the Product... Direct-Ship Only**

**Is the Product... Unit of Use**

**Orphan Drug Status**

**FDA Approval Status**

**Allergens Present**

**Country of Origin** USA

Is this product covered under the Trade Agreements Act (TAA)?  Yes

**Size:** 90ct

**Strength:** 75mcg

**Dosage Form:** Tablet

**Product Shape:** capsule shaped, biconvex tablets

**Product Color:** Violet

**Product Imprint:** plain on one side and debossed "score line 3" on the other side.

## ORDER INFORMATION

**Unit of Sale**

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Power Multi

Other: Write In

**What is the NDC selling unit?** 1 bottle of 90 tablets (Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes

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

Each

Inner/ Carton/Pack

Case

## FOR GENERIC DRUG PRODUCTS

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

**I. Orange Book Rating:** AB4

**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

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.

**GLN:** 00331722000000

**GCP:**

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.083	1.5	1.5	3	6.75	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	2.35	10	7	4.25	297.5	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		00331722286909	00331722286909
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722286906	
<input type="checkbox"/> Pallet				

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) (\$)** \$13.31

As of date: 4/5/2023

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**

\*Please provide any additional information on page 2.

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

See new p. 3 for Designated Drop Ship Only.

Signature:



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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)

- 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?  No  Yes  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:  No  Yes  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:  No  Yes

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:

