

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

| Version 2021 | | | | | | Introduction Type | : New Item | | x Final Version | | | Date: | 6/23 | 3/2024 |
|--|---------------------|---------------------|-------------------------------|----------------|--------------------|-------------------------|---|--|--------------------------------|---------------------|--------------------|---------------|---------------|------------|
| | | | PRODUCT INFORMA | TION | | | | | SPECIAL HAN | DLING AND STOR | RAGE REQUI | REMENTS* | | |
| Company Name: | Camber Pharmac | euticals, Inc. | | | | Application | : ANDA | a. Temperati | ure - Indicate the USP tempe | erature range for t | his product. | | | |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 215259 | | | | | | | Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F) | | | | | | | |
| Medical Device Class, if applicable: | | | | | | | | | | | | | | |
| DUNS: | 11-856-3719 | | | | | | | _ | Other Temperature Range | Requirement | Excursions a | allowed betwe | een 15° and 3 | 30°C (59° |
| Proprietary Name (If Applicable) a | | ame: Levo | othyroxine Sodium Tablets, US | SP 125 mca | | | | T | (write in) | | and 86°F) | | | (|
| Selling Unit NDC: | 31722-290-10 | | Unit of Use NDC | | | UPC: 33 | 1722290104 | | Notes | | | | | |
| UDI | | | CVX Code: | | | MVX Code: | | | | | | | | |
| Description: | Lougthurovino Co | dium Tablets, USP | 125 mag | | | | | i | Is this product to be shippe | to quetomore on i | 202 | | No | 1 |
| Description. | Levolityroxine 30 | didili Tablets, USF | 125 IIICg | | | | | | Is this product to be shipped | | | | No | - |
| Active Ingredient(s): Levothyroxine sodium, USP | | | | | | | | + | is this product to be shipped | 1 to customers on c | ary ice: | | 140 | 1 |
| Action in gradient (c) | | | | | | | b. Contact fo | r temperature excursion qu | estions: | | | | | |
| URL for Additional Product Inform | nation: | www.camberphar | ma.com | | | | | 1 | Name: | | Soma Raju | | | |
| Address: | 800 Centennial A | ve, Suite 1 | | | | Address 2: | | | Number: | | 732-529-042 | 23 | | |
| City: | Piscataway | | | | NJ Z | ip: 08854 | | Group E-mail: | | somaraju@l | neterousa.coi | <u>m</u> | | |
| Key Contact: | Customer Service | e | Email: | | | customerservice@ca | mberpharma.com | | | | | | | |
| Phone Number: | 1-866-827-3647 | | | | 732-562-8788 | | c. Special regulations for product in any states? | | | | | No | 1 | |
| Product Therapeutic Classification | on: | Synthetic thyroid | hormone | | | | | | Special returns requirement | s for this product? | | | No | |
| | | | | | | | | | | | | | | 4 |
| | ADDITI | ONAL PRODUCT I | INFORMATION | | | PRODUCT DES | CRIPTION INFORMATION | d. Store product (unit of sale) upright? | | | | | 1 | |
| The product is? | | | Is the Product | Direct-Ship C | Only | | | | Protect product (unit of sa | le) from light? | | | No | i |
| a legend device? | | No | Is the Product | Neither | | | 1000 ct | e. Shelf life: | otoot product (dime or ot | , | | | 24 | Months |
| if yes, enter class # | | 110 | Orphan Drug Status | | | Size: | 1000 01 | 0.0.0 | Initial shelf life at launch (| if different): | | | | Months |
| a product kit? | | No | o.p.ia D. ag otatao | | | | 125 mcg | | muai onon mo at iaanon (| | | | | |
| if yes, list NDCs of | | 11.12 | FDA Approval Status | | | Strength: | ' ' ' ' | | | ORDER INFORM | MATION | | | |
| component parts | | | • • | | | B | Tablet | | | | | | | |
| reverse numbered? | | No | | | | Dosage Form: | | | Unit of Sale | | What is the | NDC selling | unit? | |
| co-licensed? | | No | Allergens Present | | | | | | x Bottle | | 1 Bottle of 1 | 000 Tablets | | |
| latex-free? | | Yes | Alachal | Sugar, Dye | | Product Shape: | Capsule, biconvex | | Box/Carton | | (Write-in, e. | g. 1 Box of 1 | 0 Vials) | |
| preservative-free? | | No | Alconol, | Sugar, Dye | | Froduct Snape. | | | Ampule | | | | | |
| correctional institution block? | | No | | | | Product Color: | Gray | | Glass | | Minimum o | rder quantity | <i>i</i> ? | Yes |
| opioid? | | No | | | | Froduct Color. | | | Tube | | | | | |
| Cannabinoid? | | No | Country of Origin | USA | | Product Imprint | Plain on one side and debossed 'score line 7' on the other side | | Vial Liquid Sgl | | | | | |
| If Unit Dose, is item bar coded to | unit dose for | | | | | i roddot imprint | score line 7 on the other side | | Vial Liquid Multi | | | | ich package | type? |
| hospital scanning? | | | Is this product covered | | | | | | Vial Powder Sgl | | 24 | Each | | |
| If Unit Dose, indicate NDC here: | | | Trade Agreements Act (| TAA)? | Yes | | | | Vial Powder Multi | | | Inner/Cartor | n/Pack | |
| | | | | | | | | <u> </u> | Other: Write In | | | Case | | |
| | | | FOR GENERIC DRUG PF | RODUCTS | | | | | | | | | | |
| | | | | | | | | | DI. | ADMAQY ODDED | / DILL LINE | | | |
| | | | | | Au | | Authorized Generic, other ction fields are not applicable | | | ARMACY ORDER | | | | |
| I. Orange Book Rating: | AB4 | | | | | 56 | ction fields are not applicable | Rec. sell uni | t to customer? | - | Rx billing u | nit to pharm | acy: | |
| II. Generic Equivalent to What Bra | and?: | Thyro-Tabs | | | | | | Each | | | | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | | | | | | | (Write-in, e.g | i. 1 Viai) | | | Gram Milliliter | | | |
| | | DR00 30F | PET CHAIN SECONTT ACT | (DSCSA) INI ON | MATION | | | | | | | wiiiiiitei | | |
| Does supplier meet DSCSA defini | ition of manufactu | rer? | Yes | | GLN: | 0331722498975 | | | ITEN | I AND PACKING II | NFORMATIO | N | | |
| Is product exempt from DSCSA? | | | No | | | | | | | | | | | |
| If ves. select exemption: | | | | | GCP: | | | il | | Dimonei | ions (US msn | nts) | Volume | Saleable # |
| Other exemption - Write in: | | | | | GUF. | | | _ | Weight Lbs. | Depth | Width | Height | (Cube) | Pieces |
| Is product repackaged? | | | No | | If yes, was o | riginal product purcha | sed | Item/Each: | | | | | | |
| Is product sold by manufacturer's | s exclusive distrib | utor? | Yes | | direct from m | | | | 0.34 | 2.25 | 2.25 | 4.25 | 21.52 | 1 |
| Has FDA granted waiver/exceptio | | | No | \dashv | | ce manufacturer for re | packaged product | Box/Carton/I | Bundle/ | | | | | |
| If yes, attach documentation fro | | | | | | | | Inner Pack: | | | | | | |
| | | | | | | | | Case: | 8.55 | 14.5 | 10 | 5 | 725 | 24 |
| | | G | TIN AND HIBCC PRODUCT | INFORMATION | | | | | 0.55 | 14.5 | 10 | , | 125 | 24 |
| | | | | | | | | Pallet: | | | | | | |
| Saleable Unit of Measure | \$ | Saleable Quantity | HIBCC | | | N-14 | Unit of Use GTIN-14 | | | | | | | |
| X Item/Each | | 1 | | | 003 | 31722290104 | | | 0.007 | | | | ED 110E 64 | |
| Box/Carton/Bundle/Inner Pack | | | | | | | | | COST INFORMATION | | | WHOLESAL | ER USE ONL | -Y: |
| X Case | | 24 | | | 103 | 31722290101 | | 11 | _ | | l | | | |
| Pallet | | | | | | | | Regular Cos | | **** | Vendor #: | | | |
| | | | | | | | | Invoice Cost | (WAC) (\$) | \$190.22 | Whsl. Code | | | |
| | | | | | | | | An of date: | 3/13/2023 | | Fineline Co | ue: | | |
| | | | | | | | | As of date: | 3/13/2023 | | - | | | |
| | | | | | | | | | | | | | | |
| ļ ' | | | Attach copy of SAFETV D | ΔΤΔ SHEET (SD | IS) or non baza | ard letter PACKAGE INIC | SERT, LABEL AND PHOTO OF | PRODUCT PACK | AGING and BARCODE | | | | | |
| *Please provide any additional inf | formation on page | 2. | , and on dopy of Orti ETT D. | (00 | .5, 51 11011 11020 | | signated 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 | SDS Hazard Classification | | | | | |
| b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No | x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard | | | | | |
| c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? | Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: | | | | | |
| 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 | Is the product a NIOSH hazardous drug? If yes, indicate which: | | | | | |
| c. DOT Hazard Class d. Packing Group | Hazardous Waste Identification | | | | | |
| e. Inhalation Hazard? Is this product regulated for shipment by IATA? No | EPA Hazardous Waste Code: Waste Characteristics | | | | | |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number | REMS or REGISTRY RESTRICTIONS | | | | | |
| b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? | Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL: | | | | | |
| Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo | Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) | | | | | |
| 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) | REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: NCPDP#: NPI #: | | | | | |
| Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP# | Comments | | | | | |
| ADD'L STORAGE INFORMATION | Registry: Registry Program Contact Name: Comments No Phone: | | | | | |
| Is the Product | | | | | | |
| Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION: | RETURN INSTRUCTIONS Contact tel. # if product received damaged: I-866-827-3647 Is product returnable for credit: Yes | | | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes | URL/Link to returns policy: contact - customerservice@camberpharma.com | | | | | |
| Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No | Special regulations or returns requirements for this product in certain states? | | | | | |
| Restricted from US territories? (explain in comments) No Comments: | If so, which states? Other requirements? Comments? | | | | | |
| MISCELLANE | DUS NOTES and/or Image of Product Barcode: | | | | | |
| | | | | | | |



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

| Order Method fo | r Designated Drop Ship Product | Standard Order Receipt and Processing | | | | | |
|---|--|--|--|--|--|--|--|
| Purchase orders may be accepted by: a. EDI | | Purchase order daily receipt cut off time by supplier Cut off time: | | | | | |
| b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: | Fax Number: Fax Number: Phone No.: Site Address: | Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: | | | | | |
| F | Name: Phone: | Ships regular ground for 3-10 days receipt: | | | | | |
| Expedited Freight Charg | ges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing | | | | | |
| Expedited freight fees billed with each order: | | Overnight receipt available: | | | | | |
| Drop Ship service fee billed with each order: | | PO Receipt cut off time: | | | | | |
| Drop Ship miscellaneous fees billed: Comments: | | Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday | | | | | |
| | | Priority Overnight receipt available: | | | | | |
| Class | of Trade Restriction: | PO Receipt Cut off time: | | | | | |
| No restriction: Select YES if sold to retail pharmacy only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments: | offices only: | Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply: | | | | | |
| Other Data Infor | rmation Required to Process PO: | Return Instructions | | | | | |
| Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: | | 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? | | | | | |
| Mis | scellaneous Notes: | | | | | | |
| | | | | | | | |
| | | ADDITIONAL INFORMATION | | | | | |
| | | Is product order for scheduled patient procedure? Is product order for restocking purposes? | | | | | |