

Standard Pharmaceutical Product Information (Rx Product Only)

| © August 2014 | | | | | Introduction Type: | Post Launch Change | | Final Version | | | Date: | 4/18 | 8/2017 | |
|---|--|------------------------|-----------------------------------|----------------------|---------------------------------------|--|--|--|----------------|------------------------|---------------------------|------------------|----------------|--|
| | | | PRODUCT INFORMATION | N | | | | SPECIAL HANDLI | ING AND ST | ORAGE REQ | UIREMENTS | S* | | |
| Company Name: Camber Pharmaceuticals Application: ANDA | | | | | | | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | |
| Application Number for ND | NDA/ANDA/BLA (drug); PMA/510(k)(med device): 207416 | | | | | | Temper | ature Range | | Controlled F | Room – betwe | een 20 and 25 | 5 C (68° – 77° | |
| DUNS: | 82-667-4775 | | | | | | | emperature Range Re | equirement | | | | _ | |
| Proprietary Name (If Applica | able) and Established | Name: Methyl | phenidate Tablets USP 10MG 100 | CT 31722-174-0 | 4 1 1 1 1 1 1 1 1 1 | | (w | rite in) | | | | | 4 | |
| Selling Unit NDC: UDI | 31722-174-01 NA | | Individual Unit NDC: CVX Code: | 31/22-1/4-0 | 1 UPC: 33172 MVX Code: NA | 2174015 | le this n | roduct to be shipped t | o cuetomere | on ice? | | No | | |
| | | | | | | Is this product to be shipped to customers on dry ice? | | | | | | | | |
| Description: White, round tablets debossed with 'T' on one side and '174' on the other. | | | | | | | | is this product to be shipped to customers on thy ide: | | | | | | |
| Active Ingredient(s): | | Methylphenidate | | | | | b. Contact for tempera | ature excursion ques | stions: | | | | | |
| | | | | | | | Name: | | | Soma Raju | Soma Raju 732-529-0423 | | | |
| URL for Additional Product I Address: | Information: www.camberpharma.com 1031 Centennial Avenue Address 2: | | | | | | Number Group I | | | | eterousa.co | m | | |
| City: | Piscataway State: NJ Zip: 08854 | | | | | | 1 | | | comarajaæ | | | | |
| Key Contact: | Customer Service Email: customerservice@camberpharma.com | | | | | | c. Special regulations | | | | | No | _ | |
| Phone Number: | 732-529-0430 | | | Fax: | 732-562-8788 | | Special | returns requirements | for this produ | ict? | | No | _ | |
| Product Therapeutic Classification: d. Store product (unit of sale) upright? No | | | | | | | | | | | | | | |
| ADDITIONA | AL PRODUCT INFORI | MATION | | | PRODUCT DESCRIPTION I | NFORMATION | | or sale) uprignt? product (unit of sale |) from light? | , | | No No | _ | |
| Is the Product | | | | | | | e. Shelf life: | . | , g | | | 24 | Months | |
| a legend device? | | No | | Size: | 100 | | | helf life at launch (if | different): | | | | Months | |
| reverse numbered? | | No | | Size. | 100 | | | | | | | | _ | |
| co-licensed? | | No Direct-Ship Only | - | Strength: | 10 mg | | | C | ORDER INFO | RMATION | | | | |
| Is the Product | | Unit of Use | = | B | m: Oral solid tablet | | Unit of | Sale | | What is the | NDC selling | unit?□ | | |
| | | | - | Dosage For | m: Oral solid tablet | | | Bottle | | 1 box of 24 | | | | |
| If Unit Dose, is item bar code | ed to unit dose for hos | pital scanning? | _ | | | | <u>x</u> | Box/Carton | | (Write-in, e | .g. 1 Box of 1 | 0 Vials) | | |
| If Unit Dose NDC, indicate N | JDC here | | -1 | Product Sha | ape: round | | | Ampule Glass | | Minimum o | rder quantity | v? | Yes | |
| | | | - | Product Col | or: white | | | Tube | | | | , . | | |
| Country of Origin | | United States | | Product Col | or. writte | | | Vial Liquid Sgl | | | | | | |
| Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint: T'/174' | | | | | | | Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each | | | | | | | |
| | | 140 | - | | | | | Vial Power Multi | | 24 | Inner/Cartor | n/Pack | | |
| | | | | | | | | Other: Write In | _ | | Case | | | |
| | | | FOR GENERIC DRUG PRODU | ICTS | | | 4 | | | | | | | |
| | | | | Au | thorized Generic *If Au | thorized Generic, other section | PHARMACY ORDER / BILL UNIT | | | | | | | |
| I. Orange Book Rating: AB fields are not applicable | | | | | | | Rec. sell unit to customer?□ Rx billing unit | | | | | it to pharmacy: | | |
| | neric Equivalent to What Brand?: Ritalin | | | | | | | | | | Each | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | | | | | | (Write-in, e.g. 1 Vial) | | | | Gram | | | | |
| | | DRUG SUP | PLY CHAIN SECURITY ACT (DSC | SA) INFORMATION | | | | | | | Milliliter | | | |
| Does supplier meet DSCSA | definition of manufac | turer? | Yes | GLN: | | | ITEM AND PACKING INFORMATION | | | | | | | |
| Is product exempt from DSC | CSA? | | No | | | | | | | | | | | |
| If yes, select exemption: Other exemption - Write in: | | | | | | | | Weight Lbs. | Dime | nsions (US n Height | nsmts.) Width | Volume (Cube) | # Pieces: | |
| Is product repackaged? | • | | No | If Yes, was orig | inal product purchased direc | et e | Item: | 0.00 | Бериі | | | (Gubc) | | |
| Is product sold by manufact | | | No | from mfr? | | | | 0.68 | | 2.694 | 1.52 | | | |
| Has FDA granted waiver/exc | ception/exemption for | r product? | No | If yes, attach do | cumentation from FDA. | | Box/Carton/Bundle/ Inner Pack: | 2.1 | 10.8 | 3.2 | 7 | 0.14 | 24 | |
| | | | GTIN PRODUCT INFORMAT | ION | | | Case: | | | | | | + | |
| | | | Sale | able | | | 111 | | | | | | | |
| | | - | Level Ui | | Quant | | Pallet: | | | | | | | |
| Serialized? If not, when? | Yes | x | Item Box/Carton/Bundle/Inner Pack | x 2D 2D | Linear 1 Linear | 00331722174015 | UPC: | Case: | | | | | | |
| Items aggregated? | No | x | _ | x 2D | Linear 24 | 10331722174012 | III orc. | Carton: | | | | | | |
| | Pallet 2D Linear | | | | | | | | | | | | | |
| | 2D Linear 2D Lin | | | | | | COST INFORMATION WHOLESALER USE ONLY: | | | | | | | |
| | | | | 2D 2D | Linear | | Regular Cost | | | Vendor #: | | | | |
| | 2D Linear | | | | | Invoice Cost (WAC) (\$) \$28.08 | | | | | | | | |
| | | | | | | | Federal Excise Tax Pe | er Unit of Sale | | Fineline Co | de: | | | |
| | | | | | | | As of date: | | | | | | | |
| | | | Attach copy of SAFETY DATA S | HEET (SDS) or non he | azard letter PACKAGE INSEE | T LAREL AND PHOTO OF PRO | DDLICT PACKAGING and F | BARCODE | | 1 | | | | |
| *Please provide any addition | nal information on pa | na 2 | , muon oopy of on ETT DATA 3 | (000) 01 11011 118 | See new p. 3 for Designation | | Signatu | | | | | | | |



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Organic Corrosive No Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Cargo Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: No Small Quantity (49 CFR 173.4) Wholesale distributor support: No Special Permit; DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: No by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Comments Is the Product... Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Phone Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code RETURN INSTRUCTIONS Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: 732-529-0430 No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No URL/Link to returns policy: Restricted to retail pharmacy only: Yes Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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 | | | | | | |
|--|--|--|--|--|--|--|--|
| Purchase orders may be accepted by: a. EDI Yes And for the second secon | Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern | | | | | | |
| b. Autofax No Fax Number: c. Fax Yes Fax Number: d. Phone only No Phone No.: | Shipping lead time of PO: 24/48 Hours Days | | | | | | |
| e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: No Site Address: 732-529-0430 x466 x465 x467 x470 Name: Phone: | Ships same day for next day receipt: Ships for second day receipt: No Ships regular ground for 3-10 days receipt: Yes | | | | | | |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing | | | | | | |
| Expedited freight fees billed with each order: No | Overnight receipt available: Yes | | | | | | |
| Drop Ship service fee billed with each order: No No | PO Receipt cut off time: 2:30PM Eastern | | | | | | |
| Drop Ship miscellaneous fees billed: No Comments: | Days of week overnight is available: x Monday Tuesday Wednesday Thursday Friday | | | | | | |
| | Priority Overnight receipt available: Yes | | | | | | |
| Class of Trade Restriction: | PO Receipt Cut off time: 2:30PM EST | | | | | | |
| 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) No Comments: | Saturday Overnight receipt available: No | | | | | | |
| | Other fees apply: No | | | | | | |
| Other Data Information Required to Process PO: | Return Instructions | | | | | | |
| Patient Procedure Date: Physician Name: Physician/Clinic Phone # 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? | | | | | | |
| Miscellaneous Notes: | | | | | | | |
| | | | | | | | |
| | ADDITIONAL INFORMATION | | | | | | |
| | Is product order for scheduled patient procedure? Is product order for restocking purposes? No | | | | | | |