

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

| | | | | | | Introduction Typ | e: New Item | | x Final Version | | | Date: | 6/23 | |
|--|--|---|---|---------------|---|---|--|---|---|---------------------------------------|--|--|---------------------------|------------------|
| | | | PRODUCT INFORMA | TION | | | | | SPECIAL HAND | LING AND STOR | AGE REQUIF | EMENTS* | | |
| Company Name: | Camber Pharmac | euticals, Inc. | | | | Application | n: ANDA | a. Temperatur | e - Indicate the USP tempe | ature range for th | nis product. | | | |
| Application Number for NDA/AN | NDA/BLA (drug); Pl | MA/510(k)(med device | :e): | 210 | 0354 | | | | Temperature Range | Controlled Room - | - between 20 | and 25 C (68 | ° – 77° F) | |
| Medical Device Class, if applica | able: | | | | | | | | | | | | | |
| DUNS: | 11-856-3719 | | | | | | | _ | Other Temperature Range R | equirement | | | | |
| Proprietary Name (If Applicable) | | ame: Methyl | lphenidate Hydrochloride Ch | | USP 10 mg | | | | (write in) | | | | | |
| Selling Unit NDC: | 31722-928-01 | | Unit of Use NDC | | | | 31722928014 | 1 | Notes | | | | | |
| UDI | | | CVX Code: | | | MVX Code: | | | | | | | | |
| Description: | Methylphenidate | Hydrochloride Chewal | ble Tablets, USP 10 mg | | | | | T | Is this product to be shipped | to customers on ic | e? | | No | 1 |
| | | | | | | | | | Is this product to be shipped | to customers on d | ry ice? | | No | |
| Active Ingredient(s): | | Methylphenidate hy | drochloride, USP | | | | | | | | | | | |
| | | | | | | | | b. Contact for | temperature excursion que | stions: | | | | |
| URL for Additional Product Inforr | | www.camberpharma | a.com | | | | | 4 | Name: | | Soma Raju | | | |
| Address: | 800 Centennial A | ve, Suite 1 | | | Ctata | Address 2: | 7 | - 1 | Number: | | 732-529-042 | | | |
| City: | Piscataway Customer Service | State: De Email: | | | customerservice@c | Zip: 08854 | Group E-mail: somaraju@heterousa.com | | | 1 | | | | |
| Key Contact: Phone Number: | 1-866-827-3647 | , | | | Fax: | 732-562-8788 | amberphama.com | c Special reg | ulations for product in any | tates? | | | *Yes | 1 |
| Product Therapeutic Classification | | Central nervous sys | stem (CNS) stimulant | | l ux. | 702 002 0700 | | C. Special reg | Special returns requirements | | | | *Yes | |
| Froduct merapeutic classification | on. | Ochtral Hervous sys | sterri (6146) stirridiant | | | | | | Special returns requirements | ioi tilis pioduct: | | | 163 | J |
| | ADDIT | ONAL PRODUCT IN | FORMATION | | | PRODUCT DE | SCRIPTION INFORMATION | d Store produ | uct (unit of sale) upright? | | | | No | 1 |
| | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | | Direct-Ship O | Amilia. | 1 1105001 52 | | a. otore prout | | | | | |] |
| The product is? | | No | Is the Product | Neither | лпу | | 100 ct | a Chalf life. | Protect product (unit of sal | e) from light? | | | No 24 | Manaka |
| a legend device? if yes, enter class # | | INO | Is the Product Orphan Drug Status | INCILIE | | Size: | 100 Ct | e. Shelf life: | Initial shelf life at launch (if | different). | | | 24 | Months Months |
| a product kit? | | No | Orphan Drug Status | | | | 10 mg | | illitiai Shell lile at laulich (il | unierent). | | | | WOITIIS |
| if yes, list NDCs of | | 110 | FDA Approval Status | | | Strength: | · · · · · · · · | | | ORDER INFORM | ATION | | | |
| component parts | | | | | | Dosage Form: | Chewable 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 | | | |
| latex-free? | | Yes | Lactose, Dairy, Corn, | | I, Sugar, | Product Shape | Flat, round | | Box/Carton | | (Write-in, e. | j. 1 Box of 10 |) Vials) | |
| preservative-free? | | Yes | Rennet, Ca | assein, Whey | | • | | | Ampule | | | | _ | |
| correctional institution block? | | No | | | | Product Color: | White to off-white | | Glass | | Minimum or | der quantity | ? | Yes |
| opioid? Cannabinoid? | | No No | Country of Origin | USA | | | Debossed with 'AT' on left side and | | Tube Vial Liquid Sgl | | | | | |
| If Unit Dose, is item bar coded to | unit does for | INO | Country of Origin | USA | | Product Imprin | '262' on the right side of the bisect | | Vial Liquid Sgi | | If Yes, how | nany of whi | ch nackage | tvne? |
| hospital scanning? | unit dose for | | Is this product covered | under the | | | line and other side plain | | Vial Powder Sql | | | Each | on package | type: |
| If Unit Dose, indicate NDC here: | | | Trade Agreements Act (| | Yes | | | | Vial Powder Multi | | | Inner/Carton | /Pack | |
| | | | | | | | | | Other: Write In | | | Case | | |
| | | | | ABUATA | | _ | | | | | | | | |
| | | | FOR GENERIC DRUG PF | RODUCIS | | | | | | | | | | |
| | | | FOR GENERIC DRUG PE | RODUCIS | | | | | | | | | | |
| | | | FOR GENERIC DRUG PE | RODUCIS | Au | uthorized Generic *I | f Authorized Generic, other | | PHA | ARMACY ORDER | / BILL UNIT | | | |
| I. Orange Book Rating: | AB | | FOR GENERIC DRUG PR | RODUCIS | Au | | f Authorized Generic, other ection fields are not applicable | Rec. sell unit | | ARMACY ORDER | | it to pharma | ıcv: | |
| I. Orange Book Rating: | | Methylin Chewable | FOR GENERIC DRUG PR | RODUCTS | Au | | | Rec. sell unit | | ARMACY ORDER | / BILL UNIT Rx billing u | i it to pharma Each | ıcy: | |
| | | | | | | | | Rec. sell unit | to customer? | ARMACY ORDER | | Each Gram | icy: | |
| | | | Y CHAIN SECURITY ACT | | | | | T | to customer? | ARMACY ORDER | | Each | icy: | |
| II. Generic Equivalent to What Bra | and?: | DRUG SUPPL | Y CHAIN SECURITY ACT | | RMATION | s | | T | to customer? | | Rx billing u | Each Gram Milliliter | icy: | |
| II. Generic Equivalent to What Bra | and?: | DRUG SUPPL | Y CHAIN SECURITY ACT | | | | | T | to customer? | ARMACY ORDER | Rx billing u | Each Gram Milliliter | icy: | |
| II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? | and?: | DRUG SUPPL | Y CHAIN SECURITY ACT | | RMATION GLN: | s | | T | to customer? | AND PACKING IN | Rx billing un | Each Gram Milliliter | | |
| II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: | and?: | DRUG SUPPL | Y CHAIN SECURITY ACT | | RMATION | s | | T | to customer? 1 Vial) | AND PACKING IN | Rx billing un | Each Gram Milliliter | Volume | Saleable # |
| II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: | and?: | DRUG SUPPL | Y CHAIN SECURITY ACT Yes No | | GLN: | 0860000397957 | ection fields are not applicable | (Write-in, e.g. | to customer? | AND PACKING IN | Rx billing un | Each Gram Milliliter | | Saleable # |
| II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? | and?: nition of manufactu | DRUG SUPPL | Y CHAIN SECURITY ACT Yes No | | GLN: GCP: If yes, was o | 0860000397957 | ection fields are not applicable | T | to customer? 1 Vial) | AND PACKING IN | Rx billing un | Each Gram Milliliter | Volume | |
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| II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptic | and?: nition of manufactu 's exclusive distribi on/exemption for p | DRUG SUPPL | Y CHAIN SECURITY ACT Yes No | | GLN: GCP: If yes, was or direct from n | 0860000397957 | ection fields are not applicable | (Write-in, e.g. | to customer? 1 Vial) ITEM Weight Lbs. 0.19 | AND PACKING IN Dimensi Depth | Rx billing un | Each Gram Milliliter ts.) Height | Volume (Cube) | Pieces |
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| II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptic | and?: nition of manufactu 's exclusive distribi on/exemption for p | DRUG SUPPL | Y CHAIN SECURITY ACT Yes No No Yes | (DSCSA) INFOR | GLN: GCP: If yes, was or direct from n | 0860000397957 riginal product purch: | ection fields are not applicable | (Write-in, e.g. | to customer? 1 Vial) ITEM Weight Lbs. 0.19 | AND PACKING IN Dimensi Depth | Rx billing un | Each Gram Milliliter ts.) Height | Volume (Cube) | Pieces |
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL HA | NZARD CLASSIFICATION and TRANSPORTATION | | | | | |
|---|--|--|--|--|--|--|
| Is this product (check all that apply): | | | | | | |
| a. Cytotoxic? | SDS Hazard Classification | | | | | |
| b. CA Prop. 65 Carcinogen or Reproductive Toxicant? | x Organic Corrosive | | | | | |
| Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No | x Organic Corrosive Inorganic Oxidizer | | | | | |
| Does the product label bear a CA Prop 65 warning? | Steroid/Androgen Contact Hazard | | | | | |
| | | | | | | |
| c. Contact Hazard? | Does the product have an Aerosol class? If yes, No | | | | | |
| d. Does this product require special clean-up instructions? | identify NFPA Storage Level: | | | | | |
| (If yes, attach SDS with special instructions.) | NFPA Storage Level: | | | | | |
| e. Does the product contain DEHP? | | | | | | |
| Is this product regulated for shipment by DOT? | Is the product a NIOSH hazardous drug? | | | | | |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number | If yes, indicate which: | | | | | |
| b. Proper Shipping Name | | | | | | |
| c. DOT Hazard Class | Hazardous Waste Identification | | | | | |
| d. Packing Group | | | | | | |
| e. Inhalation Hazard? | EPA Hazardous Waste Code: Waste Characteristics | | | | | |
| Is this product regulated for shipment by IATA? | | | | | | |
| (if yes, answer a-e below and provide SDS) | REMS or REGISTRY RESTRICTIONS | | | | | |
| a. UN/Identification Number b. Proper Shipping Name | Is there a REMS on this product? | | | | | |
| c. DOT Hazard Class | If Yes, is it managed with a pharmacy registry? | | | | | |
| d. Packing Group | Website URL: | | | | | |
| e. Inhalation Hazard? | | | | | | |
| Is the product restricted for air shipment? If so, indicate restriction: | Med Guide Required No | | | | | |
| Passenger | Limited Distribution Requirement | | | | | |
| Cargo Passenger & Cargo | Comments / Details: (For example, iPledge program?) | | | | | |
| | PENO. | | | | | |
| Is this a reportable quantity? No RQ Threshold: | REMS: No REMS Program Manager Name: Phone: | | | | | |
| Is this a marine pollutant? No | Supplier Manages REMS registry exclusively: | | | | | |
| Is this product shipped utilizing an authorized DOT exception or Special Permit? | Wholesale distributor support: | | | | | |
| No (if yes, identify method below) | Provider Name: DEA #: | | | | | |
| Limited Quantity Consumer Commodity, ORM-D | Site Enrollment Number assigned by Supplier: NPI #: | | | | | |
| Small Quantity (49 CFR 173.4) | by Supplier: NPI #: | | | | | |
| Special Permit; DOT-SP | Comments | | | | | |
| Special Provision (listed in Column 7 of 49 CFR 172.101); | | | | | | |
| SP# | Registry: No | | | | | |
| ADDII OTOD LOG INFORMATION | Registry Program Contact Name: Phone: | | | | | |
| ADD'L STORAGE INFORMATION | Comments | | | | | |
| Is the Product Controlled Substance Code 1724 | RETURN INSTRUCTIONS | | | | | |
| Controlled Substance? Yes Controlled Substance Code 1724 Controlled by State(s)? Yes Listed Chemical (List I or II) No | RETURN INSTRUCTIONS | | | | | |
| ARCOS Reportable? Yes If yes, indicate which: | Contact tel. # if product received damaged: 1-866-827-3647 | | | | | |
| Schedule No. 2 Is it a scheduled listed chemical product?: No | Is product returnable for credit: | | | | | |
| CLASS OF TRADE RESTRICTION: | URL/Link to returns policy: | | | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes | contact - customerservice@camberpharma.com | | | | | |
| Restricted to retail pharmacy only: | Special regulations or returns requirements for this | | | | | |
| Restricted to hospital, clinics, and physician offices only: | product in certain states? | | | | | |
| Restricted from US territories? (explain in comments) | If so, which states? Other requirements? Comments? | | | | | |
| Comments: | DEA Form 222 or its electronic equivalent is required for all returns in all states. | | | | | |
| | | | | | | |
| MISCELLANI | OUS NOTES and/or Image of Product Barcode: | | | | | |
| *Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Par | | | | | | |
| | , | | | | | |



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

Version 2021

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

| Order Method for Designated Drop S | nip 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: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: | per: | Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: |
| Expedited Freight Charges or Other Designa | ed Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: Drop Ship service fee billed with each order: | | Overnight receipt available: 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, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments: | s and physician offices | Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply: |
| Other Data Information Required to F | rocess 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? |
| Miscellaneous Notes: | | |
| | | |
| | | ADDITIONAL INFORMATION |
| | | Is product order for scheduled patient procedure? Is product order for restocking purposes? |