

Standard Pharmaceutical Product Information (Rx Product Only)

| © August 2014 | | | | | | | Intro | duction Typ | e: | New Item | | Final Version | | | Date: | 4/19 | /2017 |
|---|--|-----------------|------------|-----------------------------------|--|--|---|--|---|---|--|--------------------------------------|---------------------------|---------------|----------------|--------------|----------------|
| | | | | PRODUCT INFORM | MATION | | | | | | | SPECIAL HANDLI | NG AND ST | ORAGE REQ | UIREMENTS | * | |
| Company Name: Camber Pharmaceuticals | | | | | Application: ANDA | | | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | | | |
| Application Number for ND | A/ANDA/BLA (drug); | PMA/510(k)(me | d device): | | 2 | 07419 | | | | | Tempera | ature Range | | Controlled R | loom – betwe | en 20 and 25 | C (68° – 77° F |
| DUNS: | 82-667-4775 | | | | | | | | | | Other Te | emperature Range Re | quirement | | | | _ |
| Proprietary Name (If Applica | | Name: | Oxycodone | and Acetaminophen T | | | | | | | (w | rite in) | | | | |] |
| Selling Unit NDC: | 31722-949-01 | | | Individual Unit NDC | >: | 31722-949-01 | | | 3172294901 | 9 | - II | | | | | | |
| UDI | | | | CVX Code: | _ | | WVX | Code: | | | | oduct to be shipped to | | | | No | - |
| Description: White, round, biconvex tablets with break line on one side and debossed with T 192' on other | | | | | | | Is this product to be shipped to customers on dry ice? No | | | | | | | | | | |
| Active Ingredient(s): Oxycodone and Acetaminophen | | | | | | b. Contact for temperature excursion questions: Name: Soma Raju | | | | | | | | | | | |
| URL for Additional Product I | nformation: | www.camberph | arma.com | | | | | | | | Number | : | | 732-529-042 | 23 | | |
| Address: | | | | | Address 2: | | | | Group E | | | | neterousa.cor | n | | | |
| City: | Piscataway | | | State: NJ Zip: 08854 | | | | | | | | | | | | | |
| Key Contact: | Customer Service | | | | Email: customerservice@camberpharma.com Fax: 732-562-8788 | | | c. Special regulations for product in any states? No Special returns requirements for this product? No | | | | - | | | | | |
| Phone Number: | 732-529-0430 | | | | Fax: 732-562-8788 | | | | | | | - | | | | | |
| Product Therapeutic Classifi | ication: | | | | | | | | | | d Stave weeduct (unit of cale) unviews? | | | | | | |
| ADDITIONA | L PRODUCT INFOR | MATION | | | | | PRODUCT | DESCRIPTIC | | ATION | d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No | | | | | | |
| Is the Product | | | | | | | | | | | e. Shelf life: | product (unit of Sale | / nom ngm. | | i | 24 | Months |
| a legend device? | | | No | | | | Г | | | | | nelf life at launch (if o | different). | | | 24 | Months |
| reverse numbered? | | | No | | | Size: | | 100 | | | | | | | | | |
| co-licensed? | | | No | | | Strength: | Ī | 5MG/325MG | | | | 0 | RDER INFO | RMATION | | | |
| Is the Product | | Direct-Ship On | ly | | | ou engin. | Ĺ | 0110/020110 | | | | | | | | | |
| Is the Product | | Unit of Use | | | | Dosage Form | : | tablet | | | Unit of S | | | | NDC selling | unit? | |
| | | | | | | | L | | | | x | Bottle Box/Carton | | 1 box of 24 I | g. 1 Box of 1 | 0 \/iale) | |
| If Unit Dose, is item bar code | ed to unit dose for hos | pital scanning? | | | | | Г | | | | | Ampule | | (winte-in, e. | g. i box oi ii | 0 viais) | |
| If Unit Dose NDC, indicate N | DC here: | | | | | Product Shap | be: | round | | | | Glass | | Minimum o | rder quantity | ? | Yes |
| | | | | | | Product Colo | r: | White to Off V | Nhite | | | Tube | | | | | |
| Country of Origin | | United States | | | | | - | | | | | Vial Liquid Sgl Vial Liquid Multi | | K Vee herr | | -h | |
| Is this product covered under | r the Trade Agreemen | ts Act (TAA)? | | | | Product Imprint: T 192' | | | Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each | | | type? | | | | | |
| | | | | | | | L | | | | | Vial Power Multi | | 24 | Inner/Carton | /Pack | |
| | | | | | | | | | | | | Other: Write In | _ | | Case | | |
| | | | F | FOR GENERIC DRUG | PRODUCTS | | | | | | _ | | | | | | |
| | | | | | | Auth | orized Gen | eric *If | | Generic, other section | | PHAR | MACY ORD | FR/BILLUNI | т | | |
| L Orongo Book Pating | AB | | | | - | //// | | | elds are not | | PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? Rx billing unit to pharmacy: | | | | | | |
| | I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Percocet | | | _ | | | | | Rec. seit unit to custo | | 1 | KX billing u | Each | acy. | | | |
| | | | | | | | | | (Write-in, e.g. 1 Vial) | | _ | | Gram | | | | |
| | | DRU | G SUPPLY | CHAIN SECURITY AC | T (DSCSA) IN | IFORMATION | | | | | | | | | Milliliter | | |
| D | | | | Yes | | iLN: | | | | | - | | | | ON | | |
| Does supplier meet DSCSA of Is product exempt from DSC | | turer? | No | | _ 0 | LN: | | | | | ITEM AND PACKING INFORMATION | | | | | | |
| If yes, select exemption: | | | | - | | | | | | | | Weight he | Dime | ensions (US m | ismts.) | Volume | # Pieces: |
| Other exemption - Write in: | | | | | | | | | | | | Weight Lbs. | Depth | Height | Width | (Cube) | # Pieces: |
| Is product repackaged? | | | No | | | Yes, was origin | al product | purchased of | lirect | | Item: | 0.14 | | 3.225 | 1.835 | | |
| Is product sold by manufactu Has FDA granted waiver/exc | | | | No No | | om mfr? yes, attach doc | umentation | n from FDA | | | Box/Carton/Bundle/ | | | | | | |
| Thas I by granted warver/exe | ephoniexemption for | product: | | 110 | - " | yes, attach 400 | amentation | in noin i bA. | | | Inner Pack: | 3.11 | 12.3 | 3.8 | 8.3 | 0.225 | 24 |
| | | | | GTIN PRODUCT INFO | RMATION | | | | | | Case: | 1 | | | | | |
| | | | | | Saleable | | | | | | | | | | | | |
| | | | <u> </u> | Level | Unit | x 2D | | | | GTIN-14 | Pallet: | | | | | | |
| Serialized? If not, when? | Yes | - | x Ite | em ox/Carton/Bundle/Inner Pack | x | x 2D x 2D | | Linear | | 00331722949019 10331722949016 | UPC: | Case: | | | | | |
| Items aggregated? | No | _ | | ase | ^ | 2D 2D | | Linear | 24 | 10331722343010 | UFC. | Carton: | | | | | |
| | | - | | allet | | 2D | | Linear | | | | | | | | | |
| | | | | | | 2D | | Linear | | | COST | INFORMATION | | | WHOLESAL | ER USE ONI | .Y: |
| | | | | | | 2D | | Linear | | | | | | | | | |
| | | | | | - | 2D 2D | | Linear | | | Regular Cost | | £10.07 | Vendor #: | <i>#</i> . | | |
| | | | | 20 Lr | | | Linear | | | Invoice Cost (WAC) (\$ Federal Excise Tax Pe | | \$10.07 | Whsl. Code Fineline Co | | | | |
| | | | | | | | | | | | As of date: | | | | | | |
| | | | | | | | | | | | | | | | | | |
| | | | Att | ach copy of SAFETY D | ATA SHEET | (SDS) or non haz | ard letter, F | PACKAGE IN | SERT, LAB | EL AND PHOTO OF PRO | ODUCT PACKAGING and B | ARCODE. | | | | | |
| *Please provide any addition | al information on pa | ge 2. | | | | | See new | v p. 3 for Des | ignated Dr | op Ship Only. | Signatu | re: | | | | | |
| | | | | | | | | | | | | | | | | | |



Standard Pharmaceutical Product Information (Page 2)

| | ated 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? | SDS Hazard Classification | | | | | | |
| Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? | Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard | | | | | | |
| c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No | Aerosol Class; Identify NFPA Storage Level: | | | | | | |
| Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name | Hazardous Waste Identification | | | | | | |
| c. DOT Hazard Class | EPA Hazardous Waste Code: | | | | | | |
| d. Packing Group e. Inhalation Hazard? | | | | | | | |
| Is the product restricted for air shipment? If so, indicate restriction: | REMS or REGISTRY RESTRICTIONS | | | | | | |
| Passenger | Is there a REMS on this product? No | | | | | | |
| Cargo | If Yes, is it managed with a pharmacy registry? | | | | | | |
| Passenger & Cargo | Website URL: | | | | | | |
| | | | | | | | |
| Is this a reportable quantity? No | | | | | | | |
| RQ Threshold: | Comments / Details: (For example, iPledge program?) | | | | | | |
| Is this a marine pollutant? No | | | | | | | |
| Is this product shipped utilizing an authorized DOT exception or Special Permit? | | | | | | | |
| No (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 | | | | | | |
| SP# | by Supplier: PCPDP #: No | | | | | | |
| SF# | | | | | | | |
| | NPI #: No | | | | | | |
| ADD'L STORAGE INFORMATION | | | | | | | |
| Is the Product | Comments | | | | | | |
| Controlled Substance? Yes | | | | | | | |
| Controlled by State(s)? Yes | Registry: No | | | | | | |
| ARCOS Reportable? Yes | Registry Program Contact Name: Phone: | | | | | | |
| Schedule No. (inc. N for non-narcotic) n/a | Comments | | | | | | |
| | Comments | | | | | | |
| Controlled Substance Code CII- oxycodone 9143 | | | | | | | |
| Listed Chemical (List I or II) No | RETURN INSTRUCTIONS | | | | | | |
| If yes, indicate which: | | | | | | | |
| Is it a scheduled listed chemical product?: No | Contact tel. # if product received damaged: 732-529-0430 | | | | | | |
| CLASS OF TRADE RESTRICTION: | Is product returnable for credit: Yes | | | | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No | URL/Link to returns policy: contact - customerservice@camberpharma.com | | | | | | |
| | | | | | | | |
| 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: | | | | | | | |
| Comments. | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | NEOUS NOTES and/or Image of Product Barcode: | | | | | | |
| MISCELLA | NEOUS NOTES and/or image of Product barcode: | | | | | | |
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Standard Pharmaceutical Product Information (Page 3)

| FOR DESIGNATED DROP SHIP PRO | DUCT ONLY - if n | ot a designated drop ship, do not con | nplete. | |
|---|------------------------|---|---|---|
| Order Method for Designated Drop Ship Product | | Standard | Order Receipt and Proces | sing |
| Purchase orders may be accepted by: a. EDI Yes b. Autofax No Fax Number: | | Purchase order daily receipt cut off Cut off time: | time by supplier 2:30PM | Eastern |
| No Par Number. c. Fax Yes d. Phone only No e. Supplier Web Site only No Site Address: | | Shipping lead time of PO: Ships same day for next day receipt: | 24/48 Hours | Days |
| Minimum Order Quantity: case pack Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone: | | Ships for second day receipt: Ships regular ground for 3-10 days red | | No Yes |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | | Overnight and | Priority Overnight PO Pro | ocessing |
| Expedited freight fees billed with each order: No | | Overnight receipt available: | | Yes |
| Drop Ship service fee billed with each order: No | | PO Receipt cut off time: | 2:30PM | Eastern |
| Drop Ship miscellaneous fees billed: No Comments: | | Days of week overnight is availal | | xMondayxTuesdayxWednesdayxThursdayxFriday |
| | | Priority Overnight receipt available: | | Yes |
| Class of Trade Restriction: 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) Comments: | Yes Yes No No | PO Receipt C Saturday Overnight receipt availabl PO Receipt C Phone: Fax: EDI: Overnight Fees apply: Other fees apply: | e: ut off time: Yes Phone #: Yes Fax #: Yes No | 2:30PM EST No 732-562-8788 |
| Other Data Information Required to Process PO: | | | Return Instructions | |
| Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes: | | Contact # if product is received damage Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirer If so, which states? Other requirem | nents for this product in certa | 732-529-0430 Yes ain states? Yes |
| | | | | |
| | | ADI | DITIONAL INFORMATION | |
| | | Is product order for scheduled patient Is product order for restocking purpose | • | No No |