

Standard Pharmaceutical Product Information (Rx Product Only)

| © August 2014 | | | | | | Intro | oduction Type: | Pos | st Launch Change | | Final Version | | | Date: | 4/13/ | /2017 |
|---|-----------------------------------|-----------------|---------------|------------------------------|---------------------|-------------------------|---|---|--|--|------------------------------|----------------|---------------|----------------|--------------|----------------|
| | | | | PRODUCT INFORMATION | | | | | | | SPECIAL HANDLI | NG AND STO | ORAGE REQI | JIREMENTS* | | |
| Company Name: Camber Pharmaceuticals Application: ANDA | | | | | | | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | | | |
| Application Number for NDA | | | device): | | 204598 | | T. T. | | | | ture Range | ataro rango | | | en 20 and 25 | C (68° – 77° F |
| DUNS: | 82-667-4775 | | | | | | | | | | mperature Range Rec | uiromont | | | | |
| Proprietary Name (If Applicate | | Name: | Fenofibrate ' | Tablets 145MG 90CT | | | | | | - 1 | ite in) | quirement | | | | |
| | 31722-596-90 | | Ononbrato | Individual Unit NDC: | 31722-596-9 | 0 | UPC: 33172 | 22596909 | | - | , | | | | | |
| UDI | NA | - I | | CVX Code: | | | Code: NA | | | Is this pr | oduct to be shipped to | customers of | on ice? | | No | |
| Description: White, oval shaped tablets embossed with 'J' on upper punch and '136' on lower | | | | | | | | Is this product to be shipped to customers on dry ice? No | | | | | • | | | |
| Trille, oval shaped tablets embossed with 3 on upper publication 130 On lower | | | | | | | To this product to be displace to determine on any loc. | | | | | | | | | |
| Active Ingredient(s): | | Fenofibrate | | | | | | | | b. Contact for tempera | ture excursion ques | stions: | | | | |
| | | | | | | | | Name: | | | Soma Raju | | | | | |
| URL for Additional Product Information: www.camberpharma.com | | | | | | Number: 732-529-0423 | | | | | | | | | | |
| Address: | 1031 Centennial Avenue Address 2: | | | | | | Group E-mail: somaraju@heterousa.com | | | | | | | | | |
| City: Key Contact: | Piscataway Customer Service | | | | State: | State: NJ | | | | - Consoliel resolutations | fan maa dooat in amo at | -40 | | | NI- | |
| Phone Number: | Customer Service 732-529-0430 | | | Fax: 732-562-8788 | | | c. Special regulations | | | ±1? | | No No | • | | | |
| Product Therapeutic Classific | | | | | | | | | - | | | | | | | |
| d. Store product (unit of sale) upright? | | | | | | | | | | | | | | | | |
| ADDITIONA | L PRODUCT INFORM | ATION | | | | PRODUCT | T DESCRIPTION I | NFORMAT | ΓΙΟΝ | | product (unit of sale) |) from light? | , | • | No | |
| Is the Product | | | | | | | | | | e. Shelf life: | | | | 24 Months | | |
| a legend device? | | | No | | | | | | Initial shelf life at launch (if different): | | | | | | Months | |
| reverse numbered? | | | No | | Size: | | 90 | | | | , , , | , | | , | | |
| co-licensed? | | | | Strength: 145 mg | | | | ORDER INFORMATION | | | | | | | | |
| Is the Product | | Direct-Ship Onl | у | | oog | | . 10 mg | | | | | | | | | |
| Is the Product | | Unit of Use | | | Dosage Fori | m: | Oral Solid tablet | | | Unit of S | | | | NDC selling | unit? | |
| | | | | | | | | | | x | Bottle Box/Carton | | 1 box of 12 l | g. 1 Box of 10 | 0 \/iale\ | |
| If Unit Dose, is item bar coded | d to unit dose for hospi | ital scanning? | | | | | | ^ | Ampule | | (vviite-iii, e. | g. I Dox of It |) viais) | | | |
| If Unit Dose NDC, indicate NE | OC here: | | | | Product Sha | ape: | Oval | | | Glass Minimum order quantity? Yes | | | | | | |
| | | | | | Product Col | or: | White | | | Tube | | | | | | |
| Country of Origin | | India | | | Floduct con | υi. | vviiite | | | | Vial Liquid Sgl | | | | | |
| Is this product covered under | the Trade Agreements | Act (TAA)? | | | Product Imp | rint: | J'/'136' | | | Vial Liquid Multi If Yes, how many of which package type? | | | | | | |
| | · · | ` ′ | No | | | | | | | Vial Powder Sql Each Vial Power Multi 12 Inner/Carton/Pack | | | | | | |
| | | | | | | | | | | -1 | Other: Write In | | 12 | Case | Pack | |
| | | | F | OR GENERIC DRUG PRODUCT | TS | | | | | | Other: Write III | 1 | | Ousc | | |
| | | | | | | | | | | | | 4 | | | | |
| | | | | | Aut | horized Gen | | | eneric, other section | PHARMACY ORDER / BILL UNIT | | | | | | |
| I. Orange Book Rating: | AB | | | | | | fields | are not ap | plicable | Rec. sell unit to custo | Rx billing unit to pharmacy: | | | | | |
| II. Generic Equivalent to What Brand?: Tricor | | | | | | | Each | | | | | | | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Wri | | | | | | (Write-in, e.g. 1 Vial) | | | | Gram | | | | | | |
| | | DRU | G SUPPLY (| CHAIN SECURITY ACT (DSCS | A) INFORMATION | | | | | | | | | Milliliter | | |
| Does supplier meet DSCSA of | lefinition of manufact | turer? | | Yes | GLN: | | | | | | ITEM AN | ND PACKING | INFORMATION | ON | | |
| Is product exempt from DSC | | | No | | 02 | | | | | - | | | | | | |
| If yes, select exemption: | | | | | | | | | | | Weight Lbs. | Dime | nsions (US m | smts.) | Volume | # Pieces: |
| Other exemption - Write in: | | | | | | | | | | | Weight Lbs. | Depth | Height | Width | (Cube) | # Fieces. |
| Is product repackaged? | | | No | | | nal product | t purchased direc | ct | | Item: | 0.25 | | 4 | 2 | | |
| Is product sold by manufactu | | | | No No | from mfr? | | f FDA | | | Box/Carton/Bundle/ | | | | | | |
| Has FDA granted waiver/exce | eption/exemption for | product? | | INO . | If yes, attach do | cumentatio | IN ITOM FDA. | | | Inner Pack: | 3.05 | 9.375 | 4.125 | 7 | 0.157 | 12 |
| | | | | GTIN PRODUCT INFORMATION | N | | | | | Case: | | | | | | |
| | | | | Saleab | | | | | | 1 | 13.75 | 14.25 | 10 | 10 | 0.825 | 48 |
| | | _ | | Level Unit | | | Quant | | ΓIN-14 | Pallet: | | | | | | 2112 |
| Serialized? | Yes | | x Iten | | x 2D | | Linear 1 | | 331722596909 | | | | | | | 2112 |
| If not, when? | | J L | | x/Carton/Bundle/Inner Pack x | x 2D | | Linear 12 | | 331722596906 | UPC: | Case: | | | | | |
| Items aggregated? | Yes | | X Cas | | x 2D 2D | - | Linear 48 | 30: | 331722596900 | | Carton: | | | | | |
| | | F | Pal | liet | 2D 2D | | Linear | | | COST | INFORMATION | | | WHOLESAL | ER USE ONL | γ. |
| | | H | - | | 2D | | Linear | | | | | | | | | ••• |
| | | Ī | | | 2D | | Linear | | | Regular Cost | | | Vendor #: | ſ | | |
| | | Į | | | 2D | | Linear | | | Invoice Cost (WAC) (\$ | | \$83.75 | Whsl. Code | #: | | |
| | | | | | | | | | | Federal Excise Tax Pe | r Unit of Sale | | Fineline Co | de: | | |
| | | | | | | | | | | As of date: | | | 1 | | | |
| | | | | | | | | | | | | | 1 | | | |
| 4D1 | | | At | ttach copy of SAFETY DATA SH | IEET (SDS) or non h | | | | | | | | | | | |
| *Please provide any addition | ai information on pac | ıe ∠. | | | | See nev | w p. 3 for Designa | ated prop | onip Uniy. | Signatu | re: | | | | | |



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL I | HAZARD CLASSIFICATION and TRANSPORTATION | | | | | | |
|--|---|---|--|--|--|--|--|
| Is this product (check all that apply): | | · | | | | | |
| a. Cytotoxic? | SDS Hazard Classification | | | | | | |
| b. CA Prop. 65 Carcinogen or Reproductive Toxicant? | ODO HAZARA GIAGGIRIGATORI | | | | | | |
| Is the product a CA Prop 65 carcinogen? | Organic Corrosive | | | | | | |
| Is the product a CA Prop 65 carcinogen? | Inorganic Oxidizer | | | | | | |
| | | | | | | | |
| Does the product label bear a CA Prop 65 warning? | Steroid/Androgen Contact Hazard | | | | | | |
| a Contact Haranda | A arread Class Identify NEDA Ctarage Levels | | | | | | |
| c. Contact Hazard? | 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? | 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 | | | | | | | |
| b. Proper Shipping Name | Hazardous Waste Identification | | | | | | |
| c. DOT Hazard Class | EPA Hazardous Waste Code: NA | | | | | | |
| 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? | | | | | | |
| Cargo | If Yes, is it managed with a pharmacy registry? | | | | | | |
| Passenger & Cargo | Website URL: | | | | | | |
| | Website ORL. | | | | | | |
| 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 No | | | | | | |
| Small Quantity (49 CFR 173.4) | Wholesale distributor support: No 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 |) | | | | | |
| <u></u> | NPI #: No |) | | | | | |
| ADD'L STORAGE INFORMATION | | | | | | | |
| Is the Product | Comments | | | | | | |
| Controlled Substance? No | | | | | | | |
| Controlled by State(s)? | Registry: No | | | | | | |
| ARCOS Reportable? No | Registry Program Contact Name: Phone: | | | | | | |
| Schedule No. (inc. N for non-narcotic) | Comments | | | | | | |
| Controlled Substance Code | | | | | | | |
| 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: | | | | | | |
| N c c | | | | | | | |
| 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: | If so, which states? Other requirements? Comments? | | | | | | |
| Restricted from US territories? (explain in comments) No | | | | | | | |
| | | | | | | | |
| Comments: | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| MISCELLAI | ANEOUS 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 b. Autofax Yes No Fax Number: | Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern | | | | | |
| c. Fax d. Phone only No Phone No.: | Shipping lead time of PO: 24/48 Hours Days | | | | | |
| e. Supplier Web Site only No Site Address: | Ships same day for next day receipt: No | | | | | |
| Minimum Order Quantity: case pack | Ships for second day receipt: No | | | | | |
| Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470 | Ships regular ground for 3-10 days receipt: Yes | | | | | |
| Contracted 3PL company / contact #: Name: Phone: | | | | | | |
| | | | | | | |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing | | | | | |
| Expedited freight fees billed with each order: No 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 | Days of week overnight is available: | | | | | |
| Comments: | x Tuesday x Wednesday Thursday x 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 No | Saturday Overnight receipt available: No | | | | | |
| Restricted to retail pharmacy only: Yes | PO Receipt Cut off time: | | | | | |
| Restricted to hospital, clinics, and physician offices only: No | Order receipt method: No Phone #: | | | | | |
| Restricted from US territories? (explain in comments) No | Fax: Yes Fax #: 732-562-8788 | | | | | |
| Comments: | EDI: Yes | | | | | |
| | Overnight Fees apply: Other fees apply: No | | | | | |
| Other Data Information Demoired to Decree DO | | | | | | |
| Other Data Information Required to Process PO: | Return Instructions | | | | | |
| Patient Procedure Date: Physician Name: | Contact # if product is received damaged: Is product returnable for credit: Yes | | | | | |
| Physician/Clinic Phone # | URL/Link to returns policy: | | | | | |
| Physician State License # | Special regulations or returns requirements for this product in certain states? Yes | | | | | |
| Physician/Clinic DEA #: | If so, which states? Other requirements? Comments? | | | | | |
| Physician/Clinic Specialty: | · | | | | | |
| Miscellaneous Notes: | | | | | | |
| | | | | | | |
| | ADDITIONAL INFORMATION | | | | | |
| | Is product order for scheduled patient procedure? | | | | | |
| | Is product order for restocking purposes? | | | | | |