

Standard Pharmaceutical Product Information (Rx Product Only)

| | | | | | Introduction Type: | Post Launch Change | | Final Version | | | Date: | 4/13 | /2017 |
|---|--|------------------------------------|---|---|--|--|--|--|-----------------------------|--|---|------------------|----------------|
| | | | PRODUCT INFORMATION | | | | | SPECIAL HANDLIN | IG AND STO | RAGE REQU | JIREMENTS' | t . | |
| Company Name: | Camber Pharmaceuti | cals | | | Application | : ANDA | a. Temperature - Indic | ate the USP tempera | ture range f | or this produ | ıct. | | |
| Application Number for ND | | | | 202843 | | | | ture Range | | | | en 20 and 25 | C (68° - 77° I |
| DUNS: | 82-667-4775 | | | | | | Other Te | mperature Range Requ | irement | | | | |
| Proprietary Name (If Applica | | Name: Monteluka | ast 10MG/30CT | | | | I | ite in) | | | | | 1 |
| Selling Unit NDC: | 31722-726-30 | | Individual Unit NDC: | 31722-726-30 | UPC: 33172 | 2726306 | T I | * | | | | | • |
| UDI | NA | | CVX Code: | | MVX Code: NA | | Is this pro | oduct to be shipped to | customers o | n ice? | | No | _ |
| Description: | Beige, round square- | shaped beige, with the up | per embossed with '114' and the | lower embossed with 'I | ľ | | Is this pro | duct to be shipped to | customers o | n dry ice? | | No | |
| | | | | | | | | | | | | | |
| Active Ingredient(s): | | Montelukast | | | | | b. Contact for tempera | ture excursion quest | ions: | | | | |
| URL for Additional Product I | nformation | www.camberpharma.con | 2 | | | | Name: Number: | | | Soma Raju 732-529-042 | 23 | | |
| Address: | 1031 Centennial Ave | | | | Address 2: | | Group E | | | somaraju@h | | n | |
| City: | Piscataway | | | State: | NJ Zip: | 08854 | 1 | | | | | | |
| Key Contact: | Customer Service Email: customerservice@camberpharma.com | | | | pharma.com | c. Special regulations for product in any states? | | | | | | _ | |
| Phone Number: | 732-529-0430 | | | Fax: | 732-562-8788 | | Special re | eturns requirements fo | r this produc | ? | | No | _ |
| Product Therapeutic Classif | ication: | | | | | | | | | | | | |
| | | | i | | | | d. Store product (unit of | | | | | No | _ |
| | AL PRODUCT INFORM | ATION | I | | PRODUCT DESCRIPTION IN | NFORMATION | - I | product (unit of sale) | from light? | | | No | = |
| Is the Product | | | I | | | | e. Shelf life: | | | | | 24 | Months |
| a legend device? | | No No | Ì | Size: | 30 | | Initial sh | elf life at launch (if di | tterent): | | | | Months |
| reverse numbered? co-licensed? | | No No | Ì | | | | | 0 | RDER INFOR | MATION | | | |
| Is the Product | | Direct-Ship Only | I | Strength: | 10 mg | | | <u> </u> | | | | | |
| Is the Product | | Unit of Use | I | Dosage Form | n: Oral solid tablet | | Unit of S | ale | | What is the | NDC selling | unit? | |
| | | | I | Dosage i oili | i. Olai soliu tablet | | | Bottle | | 1 box of 12 b | | | |
| If Unit Dose, is item bar code | ed to unit dose for hosp | ital scanning? | I | | | | x | Box/Carton | | (Write-in, e. | g. 1 Box of 1 | 0 Vials) | |
| If Unit Dose NDC, indicate N | DC here: | | I | Product Shap | pe: rounded square | | | Ampule Glass | | Minimum or | der auantity | 12 | Yes |
| ii onii bosc Nbo, indicate N | DO NOIC. | | I | Deadwet Cala | bains | | | Tube | | ······································ | uci quaitity | • | 103 |
| Country of Origin | | India | I | Product Colo | or: beige | | | Vial Liquid Sgl | | | | | |
| Is this product covered under | r the Trade Agreements | Act (TAA)? | I | Product Impr | rint: 114'/'l' | | | Vial Liquid Multi | | | | ch package | type? |
| | · · | No No | I | | | | | Vial Powder Sql Vial Power Multi | | | Each Inner/Carton | /Dook | |
| | | | | | | | <u>'</u> | Other: Write In | | 12 | Case | /rack | |
| | | | FOR GENERIC DRUG PRODU | ICTS | | | | Culcii Willo III | | | Ouou | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| I. Orange Book Rating: | | | | Auth | | norized Generic, other section | | PHARM | MACY ORDE | R / BILL UNI | Ţ. | | |
| | AB | | | Auth | | norized Generic, other section are not applicable | Rec. sell unit to custon | | MACY ORDE | R / BILL UNI Rx billing ur | nit to pharm | асу: | |
| II. Generic Equivalent to Wh | | Singulair | | Auth | | | | | MACY ORDE | | nit to pharm Each | асу: | |
| | | | Y CHAIN SECURITY ACT (DSC | | | | Rec. sell unit to custon (Write-in, e.g. 1 Vial) | | MACY ORDE | | nit to pharm Each Gram | асу: | |
| | | | Y CHAIN SECURITY ACT (DSC | | | | | | MACY ORDE | | nit to pharm Each | асу: | |
| II. Generic Equivalent to Wh. | at Brand?: definition of manufac | DRUG SUPPL | Yes | | | | | ner? | | | nit to pharm Each Gram Milliliter | асу: | |
| II. Generic Equivalent to Wh. Does supplier meet DSCSA Is product exempt from DSC | at Brand?: definition of manufac | DRUG SUPPL | ` | SSA) INFORMATION | | | | ner? | D PACKING | Rx billing un | nit to pharma Each Gram Milliliter | | |
| II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: | at Brand?: definition of manufac SA? | DRUG SUPPL | Yes | SSA) INFORMATION | | | | ner? | D PACKING Dimen | Rx billing un | nit to pharma Each Gram Milliliter | Volume | # Pieces: |
| II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in. | at Brand?: definition of manufac SA? | DRUG SUPPL | Yes No | SA) INFORMATION GLN: | fields | are not applicable | (Write-in, e.g. 1 Vial) | ITEM AN Weight Lbs. | D PACKING | INFORMATION SIONS (US me Height | nit to pharm. Each Gram Milliliter ON smts.) Width | | # Pieces: |
| II. Generic Equivalent to Wh. Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in. Is product repackaged? | at Brand?: definition of manufac SSA? | DRUG SUPPL | Yes | SA) INFORMATION GLN: | | are not applicable | | ner? ITEM AN | D PACKING Dimen | Rx billing un | nit to pharma Each Gram Milliliter | Volume | # Pieces: |
| II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in. | at Brand?: definition of manufac CSA? : turer's exclusive distr | DRUG SUPPL | Yes No | GLN: If Yes, was origin from mfr? | fields | are not applicable | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ | ITEM AN Weight Lbs. | D PACKING Dimen | INFORMATION SIONS (US me Height | nit to pharm. Each Gram Milliliter ON smts.) Width | Volume | # Pieces: |
| II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in Is product repackaged? Is product sold by manufact | at Brand?: definition of manufac CSA? : turer's exclusive distr | DRUG SUPPL | Yes No No No No | GLN: If Yes, was origin from mfr? If yes, attach doc | fields a | are not applicable | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: | ITEM AN Weight Lbs. | D PACKING Dimen | INFORMATION SIONS (US me Height | nit to pharm. Each Gram Milliliter ON smts.) Width | Volume | # Pieces: |
| II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in Is product repackaged? Is product sold by manufact | at Brand?: definition of manufac CSA? : turer's exclusive distr | DRUG SUPPL | Yes No No No No No O O O O O O O O O O O O | GLN: If Yes, was origin from mfr? If yes, attach doc | fields a | are not applicable | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ | ITEM AN Weight Lbs. | D PACKING Dimen | INFORMATION SIONS (US me Height | nit to pharm. Each Gram Milliliter ON smts.) Width | Volume | # Pieces: |
| II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in Is product repackaged? Is product sold by manufact | at Brand?: definition of manufac CSA? : turer's exclusive distr | DRUG SUPPL | Yes No No No No | If Yes, was origin from mfr? If yes, attach doc | fields a | are not applicable | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: | ITEM AN Weight Lbs. 0.1 | D PACKING Dimen Depth | INFORMATION INFORMATION INFORMATION (US mereught 3 | Each Gram Milliliter DN smts.) Width 1.5 | Volume (Cube) | 24 |
| II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in Is product repackaged? Is product sold by manufact | at Brand?: definition of manufac CSA? : turer's exclusive distr | DRUG SUPPL | Yes No No No No GTIN PRODUCT INFORMATI | If Yes, was origin from mfr? If yes, attach doc | fields a | are not applicable | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: | ITEM AN Weight Lbs. 0.1 | D PACKING Dimen Depth | INFORMATION INFORMATION INFORMATION (US mereught 3 | Each Gram Milliliter DN smts.) Width 1.5 | Volume (Cube) | |
| II. Generic Equivalent to Wh. Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in is product repackaged? is product sold by manufact Has FDA granted waiver/exc | at Brand?: definition of manufac CSA? : turer's exclusive distr ception/exemption for | DRUG SUPPL turer? butor? product? | Yes No No No No STIN PRODUCT INFORMATI Level Ur | If Yes, was origin from mfr? If yes, attach doc | ral product purchased direct cumentation from FDA. Quanti | t GTIN-14 00331722726306 | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: | Weight Lbs. 0.1 2.25 Case: | D PACKING Dimen Depth | INFORMATION INFORMATION INFORMATION (US mereught 3 | Each Gram Milliliter DN smts.) Width 1.5 | Volume (Cube) | 24 |
| II. Generic Equivalent to Wh Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc | at Brand?: definition of manufac :SA? : : :urer's exclusive distr :eption/exemption for | DRUG SUPPL turer? | Yes | If Yes, was origin from mfr? If yes, attach doc | al product purchased direct cumentation from FDA. Quanti Linear 1 Linear 24 | ty GTIN-14 | (Write-in, e.g. 1 Vial) Rem: Box/Carton/Bundle/ Inner Pack: Case: Pallet: | ITEM AN Weight Lbs. 0.1 2.25 | D PACKING Dimen Depth | INFORMATION INFORMATION INFORMATION (US mereught 3 | Each Gram Milliliter DN smts.) Width 1.5 | Volume (Cube) | 24 |
| II. Generic Equivalent to Wh. Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in is product repackaged? is product sold by manufact Has FDA granted waiver/exc | at Brand?: definition of manufac CSA? : turer's exclusive distr ception/exemption for | DRUG SUPPL turer? | Yes No No No No Sale: Level Ur Box/Carton/Bundle/Inner Pack | If Yes, was origin from mfr? If yes, attach doc | al product purchased direct cumentation from FDA. Quanti Linear 1 Linear 24 Linear 24 Linear 24 | t GTIN-14 00331722726306 | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: | Weight Lbs. 0.1 2.25 Case: Carton: | D PACKING Dimen Depth | INFORMATION INFORM | nit to pharm. Each Gram Millifiter DN smts.) Width 1.5 | Volume (Cube) | 24 4416 |
| II. Generic Equivalent to Wh. Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in is product repackaged? is product sold by manufact Has FDA granted waiver/exc | at Brand?: definition of manufac CSA? : turer's exclusive distr ception/exemption for | DRUG SUPPL turer? | Yes | If Yes, was origin from mfr? If yes, attach doc | al product purchased direct cumentation from FDA. Quanti Linear 1 Linear 24 | t GTIN-14 00331722726306 | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: | Weight Lbs. 0.1 2.25 Case: | D PACKING Dimen Depth | INFORMATION INFORM | nit to pharm. Each Gram Millifiter DN smts.) Width 1.5 | Volume (Cube) | 24 4416 |
| II. Generic Equivalent to Wh. Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in is product repackaged? is product sold by manufact Has FDA granted waiver/exc | at Brand?: definition of manufac CSA? : turer's exclusive distr ception/exemption for | DRUG SUPPL turer? | Yes | If Yes, was origin from mfr? If yes, attach doc ON able it X 2D 2D 2D 2D | al product purchased direct cumentation from FDA. Quanti Linear 1 Linear 24 Linear 24 Linear | t GTIN-14 00331722726306 | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: | Weight Lbs. 0.1 2.25 Case: Carton: | D PACKING Dimen Depth | INFORMATION INFORM | nit to pharm. Each Gram Millifiter DN smts.) Width 1.5 | Volume (Cube) | 24 4416 |
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| II. Generic Equivalent to Wh. Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in is product repackaged? is product sold by manufact Has FDA granted waiver/exc | at Brand?: definition of manufac CSA? : turer's exclusive distr ception/exemption for | DRUG SUPPL turer? | Yes | If Yes, was origin from mfr? If yes, attach doc ON able X 2D 2D 2D 2D 2D 2D 2D 2D | al product purchased direct cumentation from FDA. Quanti Linear 1 Linear 24 Linear 24 Linear | t GTIN-14 00331722726306 | Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$) Federal Excise Tax Per | Weight Lbs. 0.1 2.25 Case: Carton: | D PACKING Dimen Depth | INFORMATION INFORM | mit to pharm. Each Gram Milliliter DN smts.) Width 1.5 | Volume (Cube) | 24 4416 |
| II. Generic Equivalent to Wh. Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in is product repackaged? is product sold by manufact Has FDA granted waiver/exc | at Brand?: definition of manufac CSA? : turer's exclusive distr ception/exemption for | DRUG SUPPL turer? | Yes | If Yes, was origin from mfr? If yes, attach doc ON able X 2D 2D 2D 2D 2D 2D 2D 2D | al product purchased direct cumentation from FDA. Quanti Linear 1 Linear 24 Linear 24 Linear | t GTIN-14 00331722726306 | (Write-in, e.g. 1 Vial) | Weight Lbs. 0.1 2.25 Case: Carton: | D PACKING Dimen Depth | INFORMATIC sions (US m Height 3 4.25 | mit to pharm. Each Gram Milliliter DN smts.) Width 1.5 | Volume (Cube) | 24 4416 |
| II. Generic Equivalent to Wh. Does supplier meet DSCSA is product exempt from DSC if yes, select exemption: Other exemption - Write in is product repackaged? is product sold by manufact Has FDA granted waiver/exc | at Brand?: definition of manufac CSA? : turer's exclusive distr ception/exemption for | DRUG SUPPL turer? | Yes | If Yes, was origin from mfr? If yes, attach doc ON able x 2D 2D 2D 2D 2D 2D 2D | Linear Li | ty GTIN-14 00331722726306 20331722726300 | (Write-in, e.g. 1 Vial) Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$) Federal Excise Tax Per As of date: | Weight Lbs. 0.1 2.25 Case: Carton: INFORMATION | D PACKING Dimen Depth | INFORMATIC sions (US m Height 3 4.25 | mit to pharm. Each Gram Milliliter DN smts.) Width 1.5 | Volume (Cube) | 24 4416 |



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 | |
| 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? | | | |