



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

Version 2024 Introduction Type: Final Version Date:

| PRODUCT INFORMATION | |
|--|--|
| Company Name: | Camber Pharmaceuticals, Inc. |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 215080 |
| Medical Device Class, if applicable: | |
| DUNS: | 11-856-3719 |
| Proprietary Name (If Applicable) and Established Name: | Sirolimus Oral Solution 1 mg/mL |
| Selling Unit NDC: | 31722-316-31 |
| Unit of Use NDC: | 31722-316-60 |
| UPC: | 331722316316 |
| CVX Code: | |
| MXV Code: | |
| Description: | Sirolimus Oral Solution 1 mg/mL |
| Active Ingredient(s): | Sirolimus |
| URL for Additional Product Information: | www.camberpharma.com |
| Address: | 800 Centennial Ave, Suite 1 |
| City: | Piscataway |
| Key Contact: | Customer Service |
| Phone Number: | 1-866-827-3647 |
| Product Therapeutic Classification: | Mammalian target of rapamycin (mTOR) protein inhibitor immunosuppressant |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS* | |
|---|---|
| a. Temperature – Indicate the USP temperature range for this product. | Temperature Range: <input type="text" value="Cold – between 2 and 8 C (36° – 46° F)"/> |
| Other Temperature Range Requirement (write in) | |
| Notes | <p><small>Once the bottle is opened, the contents should be used within one month. If necessary, the patient may store the bottles at room temperatures up to 25°C (77°F) for a short period of time (e.g., not more than 15 days for the bottles).</small></p> <p><small>A single vial may only be used once for dosing, and the product may remain in the syringe for a maximum of 24 hours at room temperatures up to 25°C (77°F) or refrigerated at 2°C to 8°C (36° to 46°F). The syringe should be discarded once use. See also: the preparation instructions and inserts.</small></p> |
| Is this product to be shipped to customers on ice? | <input type="text" value="No"/> |
| Is this product to be shipped to customers on dry ice? | <input type="text" value="No"/> |
| b. Contact for temperature excursion questions: | Name: <input type="text" value="Soma Raju"/> |
| | Number: <input type="text" value="732-529-0423"/> |
| | Group E-mail: <input type="text" value="somaraju@heterousa.com"/> |
| c. Special regulations for product in any states? | <input type="text" value="No"/> |
| Special returns requirements for this product? | <input type="text" value="No"/> |
| d. Store product (unit of sale) upright? | <input type="text" value="No"/> |
| Protect product (unit of sale) from light? | <input type="text" value="No"/> |
| e. Shelf life: | <input type="text" value="18"/> Months |
| Initial shelf life at launch (if different): | <input type="text" value=""/> Months |

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|---|----------------------------------|---|------------------------------|
| The product is? | | Is the Product... Direct-Ship Only | Size: |
| a legend device? | <input type="text" value="No"/> | Is the Product... Unit of Use | 60 mL |
| if yes, enter class # | | Orphan Drug Status | Strength: |
| a product kit? | <input type="text" value="No"/> | FDA Approval Status | 1 mg/mL |
| if yes, list NDCs of component parts | | Allergens Present | Dosage Form: |
| reverse numbered? | <input type="text" value="No"/> | <input type="text" value="Soy"/> | Clear, viscous oral solution |
| co-licensed? | <input type="text" value="No"/> | Country of Origin | Product Shape: |
| latex-free? | <input type="text" value="Yes"/> | <input type="text" value="India"/> | N/A |
| preservative-free? | <input type="text" value="Yes"/> | Is this product covered under the Trade Agreements Act (TAA)? | Product Color: |
| correctional institution block? | <input type="text" value="No"/> | <input type="text" value="No"/> | Pale yellow to yellow |
| opioid? | <input type="text" value="No"/> | | Product Imprint: |
| Cannabinoid? | <input type="text" value="No"/> | | N/A |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text" value=""/> | | |
| If Unit Dose, indicate NDC here: | <input type="text" value=""/> | | |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 Bottle of 60 mL Oral Solution"/> |
| <input type="checkbox"/> Box/ Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Ampule | |
| <input checked="" type="checkbox"/> Glass | Minimum order quantity? <input type="text" value="Yes"/> |
| <input type="checkbox"/> Tube | |
| <input type="checkbox"/> Vial Liquid Sgl | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Liquid Multi | <input type="text" value="6"/> Each |
| <input type="checkbox"/> Vial Powder Sgl | <input type="text" value=""/> Inner/ Carton/ Pack |
| <input type="checkbox"/> Vial Powder Multi | <input type="text" value=""/> Case |
| <input type="checkbox"/> Other: Write In | |

| FOR GENERIC DRUG PRODUCTS | |
|--|---|
| I. Orange Book Rating: | <input type="text" value="AA"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable |
| II. Generic Equivalent to What Brand?: | <input type="text" value="Rapamune"/> |

| PHARMACY ORDER / BILL UNIT | |
|-------------------------------|---|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| <input type="text" value=""/> | <input type="text" value="Each"/> |
| (Write-in, e.g. 1 Vial) | <input type="text" value="Gram"/> |
| HCPCS J-Code: | <input type="text" value="Milliliter"/> |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|---|
| Does supplier meet DSCSA definition of manufacturer? | <input type="text" value="Yes"/> |
| Is product exempt from DSCSA? | <input type="text" value="No"/> |
| If yes, select exemption: | <input type="text" value=""/> |
| Other exemption - Write in: | |
| Is product repackaged? | <input type="text" value="No"/> |
| Is product sold by manufacturer's exclusive distributor? | <input type="text" value="Yes"/> |
| Has FDA granted waiver/exception/exemption for product? | <input type="text" value="No"/> |
| If yes, attach documentation from FDA. | |
| GLN: | <input type="text" value="086000397957"/> |
| GCP: | <input type="text" value=""/> |
| If yes, was original product purchased direct from mfr? | <input type="text" value=""/> |
| Provide source manufacturer for repackaged product | <input type="text" value=""/> |

| ITEM AND PACKING INFORMATION | | | | | | |
|----------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
| Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | Saleable # Pieces |
| | | Depth | Width | Height | | |
| Box/ Carton/ Bundle/ Inner Pack: | 0.36 | 5.93 | 2.76 | 5.51 | 90.18 | 1 |
| Case: | 2.53 | 12 | 9.05 | 6.29 | 683.09 | 6 |
| Pallet: | | | | | | |

| GTIN AND HIBCC PRODUCT INFORMATION | | | | |
|--|---------------|-------------------|-------|----------------|
| Saleable Unit of Measure | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14 |
| <input checked="" type="checkbox"/> Item/Each | N | 1 | | 00331722316316 |
| <input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | N | 6 | | 20331722316310 |
| <input type="checkbox"/> Pallet | | | | |
| | | | | |
| | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------|---|---------------------|-------------------------------|
| Regular Cost | <input type="text" value=""/> | Vendor #: | <input type="text" value=""/> |
| Invoice Cost (WAC) (\$) | <input type="text" value="\$595.00"/> | Whsl. Code #: | <input type="text" value=""/> |
| As of date: | <input type="text" value="12/19/2024"/> | Fineline Code: | <input type="text" value=""/> |

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For Designated 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?
 Is the product a CA Prop 65 carcinogen? No
 Is the product a CA Prop 65 reproductive toxicant? No
 Does the product label bear a CA Prop 65 warning? No

c. Contact Hazard? No

d. Does this product require special clean-up instructions?
 (If yes, attach SDS with special instructions.) No

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT?
 (if yes, answer a-e below and provide SDS) No

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard? No

Is this product regulated for shipment by IATA?
 (if yes, answer a-e below and provide SDS) No

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction: No

Passenger
 Cargo
 Passenger & Cargo

Is this a reportable quantity? No
 RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 No (if yes, identify method below)

Limited Quantity
 Consumer Commodity, ORM-D
 Small Quantity (49 CFR 173.4)
 Special Permit; DOT-SP
 Special Provision (listed in Column 7 of 49 CFR 172.101);
 SP#

SDS Hazard Classification

Organic
 Inorganic
 Steroid/Androgen

Corrosive
 Oxidizer
 Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No
 NFPA Storage Level:

Is the product a NIOSH hazardous drug? Yes
 If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion)

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
 If Yes, is it managed with a pharmacy registry?
 Website URL:

Med Guide Required No
 Limited Distribution Requirement
 Comments / Details: (For example, iPledge program?)

REMS: No

REMS Program Manager Name: Phone:
 Supplier Manages REMS registry exclusively:
 Wholesale distributor support:
 Provider Name: DEA #:
 Site Enrollment Number assigned by Supplier: NCPDP#:
 NPI #:

Comments

Registry: No

Registry Program Contact Name: Phone:
 Comments

ADD'L STORAGE INFORMATION

Is the Product...
 Controlled Substance? No Controlled Substance Code
 Controlled by State(s)? No Listed Chemical (List I or II) No
 ARCOS Reportable? No If yes, indicate which:
 Schedule No. Is it a scheduled listed chemical product?: No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: Yes

URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Sirolimus oral solution provided in bottles may develop a slight haze when refrigerated. If such a haze occurs, allow the product to stand at room temperature and shake gently until the haze disappears. The presence of this haze does not affect the quality of the product.



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

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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 |
|--|--|
| <p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p> | <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction: | |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p> | |
| Other Data Information Required to Process PO: | Return Instructions |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> | <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> |
| Miscellaneous Notes: | ADDITIONAL INFORMATION |
| <p><input type="text"/></p> | <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> |