



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 5/16/2025

| PRODUCT INFORMATION  |  |   |                   | SPECIAL HANDLING AND STORAGE REQUIREMENTS*   |                |                     |  |
|--|--|---|-------------------|--|----------------|---------------------|--|
| <div>Company Name: Camber Pharmaceuticals, Inc.</div> <div>Application Number for NDA/ANDA/BLA; PMA/510(k): 208119      Application: ANDA</div> <div>Medical Device Class, if applicable:      NDA 505(b) Type: NOT APPLICABLE</div> <div>DUNS: 11-856-3719</div> <div>Proprietary Name (If Applicable) and Established Name: Mycophenolate Mofetil Tablets, USP 500 mg</div> <div>Selling Unit NDC: 31722-879-01      Unit of Use NDC:      UPC: 331722879019</div> <div>UDI:      CVX Code:      MVX Code:</div> <div>Description: Mycophenolate Mofetil Tablets, USP 500 mg</div> <div>Active Ingredient(s): Mycophenolate mofetil, USP</div> <div>URL for Additional Product Information: <a href="http://www.camberpharma.com">www.camberpharma.com</a></div> <div>Address: 800 Centennial Ave, Suite 1      Address 2:</div> <div>City: Piscataway      State: NJ      Zip: 08854</div> <div>Key Contact: Customer Service      Email: <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a></div> <div>Phone Number: 1-866-827-3647      Fax: 732-562-8788</div> <div>Product Therapeutic Classification: Antimetabolite immunosuppressant</div> |  |   |                   | <div>a. Temperature – Indicate the USP temperature range for this product.</div> <div>Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)</div> <div>Other Temperature Range Requirement (write in): Excursions permitted to 15°C to 30°C (59°F to 86°F).</div> <div>Notes:</div> <div>Is this product to be shipped to customers on ice? <input type="checkbox"/> No</div> <div>Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No</div> <div>b. Contact for temperature excursion questions:</div> <div>Name: Soma Raju</div> <div>Number: 732-529-0423</div> <div>Group E-mail: <a href="mailto:somaraju@heterousa.com">somaraju@heterousa.com</a></div> <div>c. Special regulations for product in any states? <input type="checkbox"/> No</div> <div>Special returns requirements for this product? <input type="checkbox"/> No</div> <div>d. Store product (unit of sale) upright? <input type="checkbox"/> No</div> <div>Protect product (unit of sale) from light? <input type="checkbox"/> No</div> <div>e. Shelf life: 24 Months</div> <div>Initial shelf life at launch (if different): Months</div> |                |                     |  |
| ADDITIONAL PRODUCT INFORMATION   |  |   |                   | PRODUCT DESCRIPTION INFORMATION  |                |                     |  |
| <div>The product is?</div> <div>a legend device? <input type="checkbox"/> No</div> <div>if yes, enter class #</div> <div>a product kit? <input type="checkbox"/> No</div> <div>if yes, list NDCs of component parts</div> <div>reverse numbered? <input type="checkbox"/> No</div> <div>co-licensed? <input type="checkbox"/> No</div> <div>latex-free? <input type="checkbox"/> Yes</div> <div>preservative-free? <input type="checkbox"/> Yes</div> <div>correctional institution block? <input type="checkbox"/> No</div> <div>opioid? <input type="checkbox"/> No</div> <div>Cannabinoid? <input type="checkbox"/> No</div> <div>If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/></div> <div>If Unit Dose, indicate NDC here:</div>  |  | <div>Is the Product... Direct-Ship Only <input type="checkbox"/> Neither <input type="checkbox"/></div> <div>Is the Product... Orphan Drug Status <input type="checkbox"/></div> <div>FDA Approval Status</div> <div>Allergens Present</div> <div>Alcohol <input type="checkbox"/></div> <div>Country of Origin: India</div> <div>Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No</div> |                   | <div>Size: 100 ct</div> <div>Strength: 500 mg</div> <div>Dosage Form: Film coated tablet</div> <div>Product Shape: Capsule, biconvex</div> <div>Product Color: Lavender</div> <div>Product Imprint: Debossed with "M12" on one side and "11" on the other side</div>   |                |                     |  |
| FOR GENERIC DRUG PRODUCTS  |  |   |                   |  |                |                     |  |
| <div>I. Orange Book Rating: AB</div> <div>II. Generic Equivalent to What Brand?: Cellcept</div>  |  |   |                   | <div><input type="checkbox"/> Authorized Generic      *If Authorized Generic, other section fields are not applicable</div>  |                |                     |  |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION   |  |   |                   |  |                |                     |  |
| <div>Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes <input type="checkbox"/> No</div> <div>Is product exempt from DSCSA? <input type="checkbox"/> No</div> <div>If yes, select exemption: Other exemption - Write in:</div> <div>Is product repackaged? <input type="checkbox"/> No</div> <div>Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes <input type="checkbox"/> No</div> <div>Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No</div> <div>If yes, attach documentation from FDA.</div>   |  |   |                   | <div>GLN: 0331722498975</div> <div>GCP:</div> <div>If yes, was original product purchased direct from mfr? <input type="checkbox"/></div> <div>Provide source manufacturer for repackaged product</div>  |                |                     |  |
| GTIN AND HIBCC PRODUCT INFORMATION   |  |   |                   |  |                |                     |  |
| Saleable Unit of Measure   |  | RFID tag(Y/N)   | Saleable Quantity | HIBCC  | GTIN-14        | Unit of Use GTIN-14 |  |
| <input checked="" type="checkbox"/> Item/Each  |  | N   | 1                 |  | 00331722879019 |                     |  |
| <input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack  |  | N   | 24                |  | 20331722879013 |                     |  |
| <input checked="" type="checkbox"/> Case   |  |   |                   |  |                |                     |  |
| <input checked="" type="checkbox"/> Pallet   |  |   |                   |  |                |                     |  |

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
Is the product a CA Prop 65 carcinogen?   
Is the product a CA Prop 65 reproductive toxicant?   
Does the product label bear a CA Prop 65 warning?

- c. Contact Hazard?
- d. Does this product require special clean-up instructions?  
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

Is this product regulated for shipment by DOT?  
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is this product regulated for shipment by IATA?  
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

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#

### ADD'L STORAGE INFORMATION

Is the Product...

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

### 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:

### SDS Hazard Classification

- ☒ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen

Does the product have an Aerosol class? If yes,  
identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

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?

If Yes, is it managed with a pharmacy registry?

Website URL:

[www.MycophenolateREMS.com](http://www.MycophenolateREMS.com)

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

#### REMS:

REMS Program Manager Name:

Allison Prezioso

Phone: 732-529-0430 ext. 465

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned

NCPDP#:

by Supplier:

NPI #:

Comments

#### Registry:

Registry Program Contact Name:

REMS Call Center

Phone: 1-800-617-8191

Comments

Mycophenolate Mofetil REMS is a shared REMS program.

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

1-866-827-3647

Is product returnable for credit:

URL/Link to returns policy:

[contact - customerservice@camberpharma.com](mailto:contact-customerservice@camberpharma.com)

Special regulations or returns requirements for this  
product in certain states?

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Mycophenolate mofetil tablets should not be crushed. Follow applicable special handling and disposal procedures in "OSHA Hazardous Drugs." <http://www.osha.gov/SLTC/hazardousdrugs/index.htm>

Release DATE



# 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> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <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><b>Purchase order daily receipt cut off time by supplier</b></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>  |
| <p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <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><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b> <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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <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> |
| <p><b>Class of Trade Restriction:</b></p> <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>  |   |
| <p><b>Other Data Information Required to Process PO:</b></p> <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><b>Return Instructions</b></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>  |
| <p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>  | <p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |