

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

Version 2024						Introduction Type	: New Item	x	Final Version			Date:	5/16	/2025
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac					Application		a. Temperature – Ind	licate the USP temp					
Application Number for NDA/AN		(k): 208119				NDA 505(b) Type:	NOT APPLICABLE	Tempe	erature Range	Controlled Room -	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applical														
DUNS:	11-856-3719		enolate Mofetil Tablets, US	D 500					Temperature Range	Requirement	Excursions p 30°C (59°F t		5°C to	
Proprietary Name (If Applicable) a Selling Unit NDC:	31722-879-01	ame: Mycopn	Unit of Use NDC:	P 500 mg		UPC: 33	1722879019	Notes	(write in)		30 C (59 F I	0 00 F).		
UDI	0.1.22 0.0 0.		CVX Code:			MVX Code:	1722073013	Notes						
Description: Mycophenolate Mofettil Tablets, USP 500 mg Is this product to be shipped to customers on ice? No								1						
2 coonpacin	,		9						product to be shippe				No	1
Active Ingredient(s):		Mycophenolate mofe	til, USP											-
								b. Contact for tempe		estions:	Soma Raju			
URL for Additional Product Inform Address:	800 Centennial A	www.camberpharma.	.com			Address 2:		Name Numb			732-529-042	3		
City:	Piscataway	ve, cuite i			State:		ip: 08854		E-mail:		somaraju@h		m	
Key Contact:	Customer Service	•			Email:	customerservice@ca								
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulation	s for product in any	states?			No	
Product Therapeutic Classificatio	n:	Antimetabolite immu	nosuppressant					Specia	al returns requiremen	ts for this product?			No	
	ADDITI	ONAL PRODUCT INF	ORMATION			PROPUCT DES	CRIPTION INFORMATION	1					N.	1
	ADDITI	UNAL PRODUCT INF		D: 101:0		PRODUCT DES	CRIPTION INFORMATION	d. Store product (un					No	
The product is?		N.	Is the Product	Direct-Ship Or Neither	nly		100 ct	e. Shelf life:	ct product (unit of sa	ale) from light?			No 24	Mantha
a legend device? if yes, enter class #		No	Orphan Drug Status	Neitriei		Size:	100 Ct		shelf life at launch (	if different).			24	Months Months
a product kit?		No	o.p.ia Drug otatao			24	500 mg		onon mo at launon (					
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts						Dosage Form:	Film coated tablet							
reverse numbered? co-licensed?		No	Allergens Present					Unit o	of Sale Bottle		What is the 1 Bottle of 10		unit?	
latex-free?		No Yes					Capsule, biconvex		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Alc	ohol		Product Shape:	Capcaio, Bioditrox		Ampule		(**************************************	g. 1 Dox of 1	J vidio,	
correctional institution block?		No				Product Color:	Lavender		Glass		Minimum or	der quantity	/?	Yes
opioid?		No					Debossed with 'M12' on one side and		Tube					
Cannabinoid?  If Unit Dose, is item bar coded to u	unit dana fan	No	Country of Origin	India		Product Imprint:	'H' on the other side		Vial Liquid Sgl Vial Liquid Multi		If Van haw		ich package i	h
hospital scanning?	unit dose for		Is this product covered up	nder the					Vial Powder Sgl			Each	сп раскаде	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No				Vial Powder Multi			Inner/Carton	ı/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS										
					Δ.,	thorized Generic *If	Authorized Generic, other		DI.	HARMACY ORDER	/ BILL LINIT			
I. Orange Book Rating:	AB				Au		ction fields are not applicable	Rec. sell unit to cust		IARMAOT ORDER	Rx billing u	-14 4		
II. Generic Equivalent to What Bra		Cellcept						Nec. sen unit to cust	omer:	1	KX billing u	Each	acy.	
								(Write-in, e.g. 1 Vial)		_		Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION			HCPCS J-Code:		-		Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes	7	GLN:	0331722498975		J75		AND PACKING IN	IFORMATION	J		
Is product exempt from DSCSA?	ation of manadacta		No	-	OLIV.	0001722430370						•		
If yes, select exemption:					GCP:			i		Dimensio	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Yes			riginal product purcha	sed	Item/Each:	0.28	2.18	2.18	3.88	18.44	1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			No	-	direct from m	וזר <i>?</i> ce manufacturer for re	nackaged product	Box/Carton/Bundle/					-	
If yes, attach documentation from		- Jount's	110		Flovide Soul	ce manufacturer for re	packageu product	Inner Pack:						
l								Case:	7.4	13.5	9.5	5.25	673.31	24
		GTIN	AND HIBCC PRODUCT IN	NFORMATION					7.4	10.0	0.0	0.20	070.01	24
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GTIN-14	Pallet:						
Saleable Still of Wedsale	Trib tag(1/14)	Quantity	TIIDOC		011	14-14	Offic of Ose Offit-14							
x Item/Each	N	1			003	31722879019								
Box/Carton/Bundle/Inner Pack								CC	OST INFORMATION			WHOLESALI	ER USE ONL	-Y:
X Case	N	24			203	31722879013					Vande - #			
Pallet								Regular Cost Invoice Cost (WAC)	(\$)	\$40.14	Vendor #: Whsl. Code	#-		
								MITOICE SUST (TTAC)	(₹/	φ40.14	Fineline Code			
								As of date:	4/22/2025					
L			A#	TA OUETT (ST	0)		DEDT LADEL AND DUCTO TO	DODUOT DA SUA SUI S						
*Please provide any additional inf	formation on neces		Auach copy of SAFETY DA	IA SHEET (SDS	or non haza ره		SERT, LABEL AND PHOTO OF F signated Drop Ship Only.	PRODUCT PACKAGING a Signa						
	on page					p. o .o. De	2. op 3mp 3mj.	Gigiia						



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

#### Version 2024

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	SDS Hazard Classification						
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?  No  Does the product label bear a CA Prop 65 warning?  No	x     Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard						
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?  No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:						
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	Is the product a NIOSH hazardous drug?  If yes, indicate which:  Group 2 items (non-antineoplastic that meets a hazard criterion)						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?  (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:  Yes  No  www.MycophenolateREMS.com						
Is the product restricted for air shipment? If so, indicate restriction:  Passenger  Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
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)	REMS Program Manager Name:  REMS Program Manager Name:  Supplier Manages REMS registry exclusively:  Wholesale distributor support:  Provider Name:  Site Enrollment Number assigned by Supplier:  Yes  Allison Prezioso No  DEA #:  NCPDP#:  NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry: Yes						
	Registry Program Contact Name: REMS Call Center Phone: 1-800-617-8191						
ADD'L STORAGE INFORMATION	Comments Mycophenolate Mofetil REMS is a shared REMS program.						
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  No  ARCOS Reportable?  No  If yes, indicate which:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No	Special regulations or returns requirements for this product in certain states?  No						
Restricted from US territories? (explain in comments)  Comments:	If so, which states? Other requirements? Comments?						
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:						
Mycophenolate mofetil tablets should not be crushed. Follow applicable special handling and disposal p	rocedures in "OSHA Hazardous Drugs." http://www.osha.gov/SLTC/hazardousdrugs/index.htm						



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

#### Version 2024

### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Purchase order ally receipt cut off time by supplier  a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No.  Expedited freight Charges or Other Designated Drop Ship Fees:  Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:
d. Phone only e. Suppler Web Site only Site Address:  Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Days of week overnight for ceipt: Days of week overnight for ships for ceipt files: Days of week overnight for ships for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days			
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL. company / contact #: Name: Phone:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees bi			Shipping lead time of PO: Hours Days
Minimum Order Quantity: Supplier's Coutement Service Number: Contracted 3PL company / contact #: Name: Phone:  Expedited Freight Charges or Other Designated Drop Ship Fees:  Expedited Freight Charges or Other Designated Drop Ship Fees:  Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:  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)  Other Data Information Required to Process PO:  Patient Procedure Data: Physician Clinic Specially:  Mitcellaneous Notes:  Mitcellaneous Notes:  Ships rescond day receipt: Ships regular ground for 3-10 days receipt:  Overnight receipt available: Drop Receipt cut off time: Days of week overnight is available: Drop Receipt cut off time: Days of week overnight is available: Proficity Overnight receipt available: Po Receipt Cut off time: Drop Receipt Cut off	,		China annua dan faranat dan mariat
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