

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

Version 2024						Introduction Ty	pe: New Item		x Final Version			Date:	5/16/	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					on: ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	NDA/BLA; PMA/510	0(k):	208119			NDA 505(b) Type:	NOT APPLICABLE		mperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applica	able:													
DUNS:	11-856-3719							Oti	her Temperature Range	Requirement		permitted to 1	5°C to	
Proprietary Name (If Applicable) a		ame:	Mycophenolate Mofetil Tablets, US	P 500 mg					(write in)		30°C (59°F	to 86°F).		
Selling Unit NDC:	31722-879-05		Unit of Use NDC:				331722879057	No	ites					
UDI			CVX Code:			MVX Code:								
Description:	Mycophenolate N	Mofetil Tablets, U	JSP 500 mg						this product to be shippe				No	
								ls t	this product to be shippe	d to customers on	dry ice?		No	
Active Ingredient(s):		Mycophenola	te mofetil, USP					h Contact for ton	nperature excursion qu	ections				
URL for Additional Product Inform	mation:	www.camberr	nharma com						me:	estions.	Soma Raju			
Address:	800 Centennial A		<u> </u>			Address 2:		-	ımber:		732-529-042	23		
City:	Piscataway				State:	NJ	Zip: 08854		oup E-mail:		somaraju@l	heterousa.cor	<u>n</u>	
Key Contact:	Customer Service	е			Email:	customerservice@	camberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulat	tions for product in any	states?			No	
Product Therapeutic Classification	on:	Antimetabolite	e immunosuppressant					Sp	ecial returns requiremen	ts for this product?			No	
								_						7
	ADDIT	IONAL PRODU	CT INFORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only				otect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	500 ct	e. Shelf life:					24	Months
if yes, enter class #		INT.	Orphan Drug Status				500	Ini	tial shelf life at launch (if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	500 mg			ORDER INFOR	MATION			
component parts			1 DA Approvar Status				Film coated tablet			011321111111111111111				
reverse numbered?		No				Dosage Form:	i iiii seatea tabiet	Un	it of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 5	00 Tablets		
latex-free?		Yes	Δlc	ohol		Product Shap	Capsule, biconvex		Box/Carton		(Write-in, e.	.g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Aic	01101		1 Todact Griup			Ampule					
correctional institution block?	•	No				Product Color	Lavender		Glass		Minimum o	rder quantity	?	Yes
opioid?		No	O	India			Debossed with 'M12' on one side and		Tube					
Cannabinoid? If Unit Dose, is item bar coded to	unit dose for	No	Country of Origin	iliula		Product Impri	nt: 'H' on the other side		Vial Liquid Sgl Vial Liquid Multi		If Voe how	many of whi	ch package t	tuno?
hospital scanning?	unit dose for		Is this product covered u	nder the					Vial Powder Sql			Each	cii package i	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Powder Multi			Inner/Carton	/Pack	
		-							Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
									D.	LADMAOV ODDER	/ DU L LINET			
				_	Au		*If Authorized Generic, other section fields are not applicable			HARMACY ORDER				
I. Orange Book Rating:	AB	0.11					section fields are not applicable	Rec. sell unit to c	ustomer?		Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bra	and?:	Cellcept						(Write-in, e.g. 1 V	ial)			Each Gram		
		DRUG S	SUPPLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			HCPCS J-Code:	iai)			Milliliter		
									J7517			_		
Does supplier meet DSCSA defin		irer?	Yes		GLN:	0331722498975			ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?	•		No											
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msr	•	Volume	Saleable #
Other exemption - Write in:			.,					1	igiit Eb5.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	o evelueire dist	utor2	No Yes		If yes, was or direct from n	riginal product purch	nased	Item/Each:	1.15	3.85	3.85	6.75	100.05	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	-			repackaged product	Box/Carton/Bund	lle/					
If yes, attach documentation fro					. IOTIGE SOUI	oo mananacturer IOI	. opusnugou product	Inner Pack:						
								Case:	15.05	16.5	12.5	7.75	1598.44	12
			GTIN AND HIBCC PRODUCT I	NFORMATION					15.05	10.5	12.5	1.15	1596.44	12
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	IN-14	Unit of Use GTIN-14							
X Item/Each	N	Quantity 1			nna	31722879057								
Box/Carton/Bundle/Inner Pack	IN	1			- 003				COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
X Case	N	12			203	31722879051								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WA	.C) (\$)	\$200.70	Whsl. Code			
								1.1						
									4/00/0005		Fineline Co	de:		
								As of date:	4/22/2025		Fineline Co	de:		
								As of date:	4/22/2025		Fineline Co	de:		
			Attach copy of SAFETY DA	ATA SHEET (SI	OS) or non haza	ard letter, PACKAGE I	NSERT, LABEL AND PHOTO OF				Fineline Co	de:		



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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	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						
(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: 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#: 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 Controlled Substance Code Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: Is product returnable for credit: 1-866-827-3647 Yes						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy: contact - customerservice@camberpharma.com						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: No							
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	EOUS 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						



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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			
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