

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

PRODUCT INFORMATION Description Description Description Application Annumber for NOANNOARUA; PANATON; Description Adjustment for NOANNOARUA; PANATON; 207022 NDA 505(b) Type: NOT APPLICABLE Temperature Range Requirement Generators and 25 C (687) Medical Device (Liss, If applicable) and Established Manue (Mocphenolate Medical Capaules, USP 220 mg UPC: 31722878012 In Temperature Range Requirement (or tein in) Excursions permitted to 15 (2000) VBL for Additional Product Information (Medical Capaules, USP 220 mg UPC: 31722878012 In Temperature Range Requirement (or tein in) Excursions permitted to 15 (2000) Excursions permitted to 15 (2000) Excursions permitted to 15 (2000) Excursions permitted to 16 (2000) Excursions permitted to 15 (2000) Excursions permitted to 16 (2000) Excursions permitted to 17 (2000) Excursions permitted to 17 (2000) Excursions permitted to 18 (2000) Excursions permitted to 18 (2000) Excursions pe	5°C to No O Vials)
Application Number for NDAMDARULA; PMA/S100;: 207022 NDA 505(b) Type: NOT APPLICABLE DURs: 11-865-3719	5°C to No O Vials)
Application Number for NDAAMDA/BLA; FMAAS100;: 277022 NDA 505(b) Type: NOT APPLICABLE DURs: 11-868-3719 Controlled Room - between 20 and 25 CBB DURS: 11-868-3719 Controlled Room - between 20 and 25 CBB DURS: 11-868-3719 Controlled Room - between 20 and 25 CBB DURS: 31722-278-21 Unit of Use NDC: UPC: 33172278012 Description: Mycophenolate Modell Capudes, USP 250 mg Excursions permitted 15 Excursions permitted 15 Active Ingrediants Product Information: Mycophenolate Modell Capudes, USP 250 mg Is this product to be shipped to customers on tor? Is this product to be shipped to customers on tor? Active Ingrediants Product Information: Mycophenolate Modell Capudes, USP 250 mg Is this product to be shipped to customers on tor? Is this product to be shipped to customers on tor? Address 2: Mix Cashes: Bit Cashes and the component of the product is? Nix Second requirement, Second requiremen	5°C to No O Vials)
DURs: 11-866-3719 Constrained and the constra	No No No No No 24 Months Months unit?
Projectiary Mane (if Applicable) and Established Mane: Mycophenolate Modell Capaules, USP 250 mg unit of Use NDC: 31722478-01 (vite in) 30°C (59°F to 80°F) Description: Mycophenolate Modell Capaules, USP 250 mg MVX Code: MVX Code: Notes Is in product to be shipped to customers on log (ce ²) Is in product to be shipped to customers on log (ce ²) Is in product to be shipped to customers on log (ce ²) Is in product to be shipped to customers on log (ce ²) Is in product to be shipped to customers on log (ce ²) Is in product to be shipped to customers on log (ce ²) URL for Additional Product Information: invacantespretame com Address 2: Name: Some and (ce) Some and (ce) URL for Additional Product Information: invacantespretame com Address 2: Name: Some and (ce) Some and (ce) URL for Additional Product Information: invacantespretame com Tip: Some and (ce)	No No No No No 24 Months Months unit?
Setting Unit NDC: UPC: 31722878012 UD UPC: 31722878012 UD Description: Mycophenolate Motell Capsules, USP 250 mg Active Ingredient(s): Mycophenolate Motell Capsules, USP 250 mg URL (or Additional Product Information: www.cantempharma.com Address :: Bio Cherinoni Al Are, Suite 1 City: Plecataway Key Contect: Customer Service Phode Number: 1:866.273.647 Product Therapeutic Classification: Nume: Address :: No Abstract No Address :: The product is? Automation is of product in any states? Sorra Raju Product Therapeutic Classification: No The product is? Is the Product	No No No No 24 Months Months unit?
VDI CVX Code: MVX Code: Description: Mycophenolate Modell Capuelles, USP 250 mg Active Ingredient(s): Mycophenolate Modell, USP Liki. for Address :: Mycophenolate modell, USP UBL. for Address :: 800 Centerminal Ave, Sue 1 City: Picadaway Very Contact: Customer Service Product Therapeutic Classification: Address 2: Number: 1:6:8::0:27/3647 Product Information: State: Description: Address 2: Address 2: Discoverse Contact for semperature securities of comber/planma.com Fore Number: 1:6:8::0:27/3647 Product Information: International Productions for product in any states? Special returns requirements for this product: Site: 1:5:: 100 ct special returns requirements for this product: Site: 0:0:contact for sealer sealer No 1:5:: 1:5:: 0:5:: 1:5:: 1:5:: 1:5:: 1:5:: 1:5:: 1:6:: 1:5:: 1:6:: 1:5::	No No No No 24 Months Months unit?
Description: Mycophenolate Motetil Capaules, USP 250 mg Is this product to be shipped to customers on ke? Is this product to be shipped to customers on ke? Is this product to be shipped to customers on ke? Is this product to be shipped to customers on ke? Is this product to be shipped to customers on ke? Is this product to be shipped to customers on ke? Is this product to be shipped to customers on ke? Is this product to be shipped to customers on ke? Is this product to be shipped to customers on ke? URL for Additional Product Information: Work camberpharma com Address: 800 Centernial Ave, Sule 1 City: Product Therapeutic Classification: Address: Castomer Service Product Therapeutic Classification: Antimetabolite immunosuppressant Product Is? Is the Product a product ki? No If yes, nist NOS of component parts concensed? No preservative-free? Yes preservative-free? Yes preservative-free? Yes product Kir? No construct Color: Balte and and Mi' on body Product Color: Balte and and Mi' on body Product Nare? No construct Researce Minimum order quantify? reverse numbered? No construct Researce	No No No No 24 Months Months unit?
Active Ingredient(s): Mycophenolate motelii, USP URL for Additional Product Information: www.cambarpharma.com Address: 800 Centennial Ave, Suite 1 Address 2: City: Prisonaway State: Product Information: Address 2: Name: City: Prisonaway State: Product Information: Address 2: Name: Product Information: Andress 2: Name: Product Information: Address 2: State: Product Information: Andress 2: State: Product Information: Andress 2: State: Product Information: Andress 2: State: If gend device? Is the Product Deret-Ship Only If gend device? Is the Product Neither Orphan Drug Status State: State: Product Kit? No If Bedre Advice? If yes, enter class # No No preservativeFre? Yes Dye, Corn preservativeFre? Yes Dye, Corn if yes, istem bar coded to unit dose for No If Bott the Product Color:	No No No No 24 Months Months unit?
Active lagredient(s): Mycophenolate moletil, USP URL for Additional Product Information: www.camberpharma.com Ward for Additional Product Information: www.camberpharma.com City: Product Information: www.camberpharma.com City: Product Name: ISOma Raju City: Product Name: ISOma Raju City: Product Name: ISOma Raju Product Therapeutic Classification: Antimetabolite immunosuppressant State: Fax: Product Is? Is the Product Direct-Ship Only a grend dvice? Is the Product Neither orphane Institution block? No Product Ship orphane Intro Status Product Shape: Capsule Product Ship No Allergens Present If Unit Dose, is lem bar coded to unit dose for Is this product (TA)? No Country of Origin India If Unit Dose, is lem bar coded to unit dose for Is this product Covered under the If Unit Dose, is lem bar coded to unit dose for Is this product Covered under the If Unit Dose, is lem bar coded to unit dose for Is this product covered under the If Un	No No No 24 Months Months unit?
URL for Additional Product Information: www.cambegrillatina.com Address :: 800 Centernial Ave, Suite 1 City: Placataway Key Contact: Customer Service Phone Number: 1-966-927-9647 Product Thrapeutic Classification: Antimetabolite immunosuppressant Abbrit Abbrit Product Thrapeutic Classification: Antimetabolite immunosuppressant Fix: 722-562-9788 Product Thrapeutic Classification: Antimetabolite immunosuppressant Fix: 722-562-9788 Product Lis? Antimetabolite immunosuppressant Fix: The product is? a legend device? No rest: Direct-Ship Only is the Product Direct-Ship Only is the Product No Product Thrapeutic Classification: Size: a product ki? No Product Shape: Product Shape: Product Shape: Product Shape: Product Shape: Product Shape: Product Inprinte: Site product Inprinte: Product Inprinte: Site product Inprinte with H on coap	No No No 24 Months unit?
URL for Additional Product Information: www.camberpharma.com Address: Some Republic Address:	No No No 24 Months unit?
Address: B00 Centennial Ave, Suite 1 Address 2: Number: 722-562-428 City: Discataway State: Discataw	No No No 24 Months unit?
Koy Contact: Customersprived Cus	No No No 24 Months unit?
Phone Number: 1-866-827-3647 Product Therapeutic Classification: Antimetabolite immunosuppressant ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION Product Si? Is the Product Direct-Ship Only a legend device? No Orphan Drug Status Size: 100 dt a product ki? No Product Status Size: 100 dt Initial sheft life at launch (if different): a product ki? No Allergens Present Size: 100 dt Size: 100 dt Initial sheft life at launch (if different): Balagend device? No Allergens Present Break Product Shape: Capsule Product Shape: Direct Ship Only I stok Product Ki? No Occurretional institution block? No Occurrty of Origin India If Unit Dose, indicate NDC here: Is the product covered under the Imprinted with "f' on cap Imprinted with "f' on body If yes, how many of which is the Inter/Catron' I unit Dose, indicate NDC here: End GeneRIC DRUG PRODUCTS For Generic DRUG PRODUCTS Imprinted with "f' on cap	No No 24 Months Months unit?
Product Therapeutic Classification: Antimetabolite immunosuppressant Special returns requirements for this product? Image: Classification: ADDITIONAL PRODUCT INFORMATION Processing Special returns requirements for this product? Image: Classification: ADDITIONAL PRODUCT INFORMATION Direct-Ship Only Special returns requirements for this product? Image: Classification: Is the Product Direct-Ship Only Size: 100 ct If yes, enter class # No Orphan Drug Status Strength: 250 mg orphan orpits FDA Approval Status Dosage Form: Hard gelatin capsule Initial shelf life at launch (if different): orpits are reverse numbered? No Allergens Present Dosage Form: Hard gelatin capsule preservative-free? Yes Dye, Corn Product Shape: Product Color: Bottle 1 Bottle of 100 Capsules product loging No Country of Origin India Product Imprint: Imprinted with 'H' on cap Minimum order quantify' If Unit Dose, indicate NDC here: Is this product covered under the Trade Agreements Act (TAA)? No Imprinted with 'H' on cap Vial Liquid Sdi If Yes, how many of whic	No No 24 Months Months unit?
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION ADDITIONAL PRODUCT INFORMATION Is the Product Direct-Ship Only a legend device? No if yes, nist class # Orphan Drug Status a product kit? No if yes, nist NDCs of Orphan Drug Status component parts PDA Approval Status PDA Approval Status Strength: 250 mg Dosage Form: Hard gelatin capsule What is the NDC selling product Shape: Capsule product Information Institution block? No opioid? No If Unit Dose, is item bar coded to unit dose for Is this product covered under the If Unit Dose, indicate NDC here: Is this product covered under the If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? No Case FOR GENERIC DRUG PRODUCTS No	No 24 Months Months unit?
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preservative-free? Yes Dye, Corn Product Shape: Ampule correctional institution block? No Product Shape: Product Shape: Class Minimum order quantity: opioid? No Country of Origin India Product Imprint: Blue cap and brown body Class Minimum order quantity: If Unit Dose, is item bar coded to unit dose for hospital scanning? Is this product covered under the Imprinted with 'H' on body Vial Liquid Multi If Yes, how many of white If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? No Vial Powder Sgl 12 Each Inner/Carton/ Other: Write In Case Case Case	
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FOR GENERIC DRUG PRODUCTS Other: Write In Case	
FOR GENERIC DRUG PRODUCTS	Pack
Authorized Generic *If Authorized Generic, other PHARMACY ORDER / BILL UNIT	
i. Orange book Rating: Ab Rec. sei unit to customer ?	cy:
II. Generic Equivalent to What Brand?: Cellcept Each (Write-in, e.g. 1 Vial)	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION HCPCs J-Code: Milling	
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 0331722498975 ITEM AND PACKING INFORMATION	
Is product exempt from DSCSA? No	
If yes, select exemption: GCP: Dimensions (US msmts.) Weight Lbs. Dimensions (US msmts.)	Volume Saleable
Other exemption - Write in:	(Cube) Pieces
Is product repackaged? No If yes, was original product purchased Item/Each: 0.20 2.5 2.5 4.82	30.13 1
Is product sold by manufacturer's exclusive distributor? Yes direct from mfr? direct from mfr? Box/Carton/Bundle/ Box/Carton/Bu	
Has FDA granted waiver/exception/exemption for product? No Provide source manufacturer for repackaged product Box/Carton/Bundle/ Inner Pack:	
	510.10
GTIN AND HIBCC PRODUCT INFORMATION 3.05 10.5 8.5 5.75	513.19 12
Pallet: Pallet:	
Saleable Unit of Measure RFID tag(Y/N) Saleable HIBCC GTIN-14 Unit of Use GTIN-14	
Quantity	
x Item/Each N 1 Box/Cartor/Bundle/Inner Pack 00331722878012 COST INFORMATION WHOLESALE	R USE ONLY:
Box/Cator/Bundle/Inner Pack N 12	N-OSE ONET.
A Case II IZ ZOUTIZZO OT IZ Regular Cost Vendor #:	
Invoice Cost (WAC) (\$) \$18.00 Whsl. Code #:	
Fineline Code:	
As of date: 1/27/2025	
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:	

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

Version 2024 For Desig	nated 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? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard
c. Contact Hazard? No d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Storage Level: Is the product a NIOSH hazardous drug? Yes
(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?	If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion) Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? No	
(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?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? Yes If Yes, is it managed with a pharmacy registry? No Website URL: 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) Special Permit; DOT-SP	Yes REMS: Yes REMS Program Manager Name: Allison Prezioso Supplier Manages REMS registry exclusively: No Wholesale distributor support: No Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:
Special Provision (listed in Column 7 of 49 CFR 172.101);	
ADD'L STORAGE INFORMATION	Registry: Yes Registry Program Contact Name: REMS Call Center Comments Mycophenolate Mofetil REMS is a shared REMS program.
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: Is it a scheduled listed chemical product?: No Schedule No. CLASS OF TRADE RESTRICTION: Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes 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: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?
Comments:	
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:
Mycophenolate mofetil capsules should not be opened or crushed. Avoid inhalation or direct contact w procedures in "OSHA Hazardous Drugs." http://www.osha.gov/SLTC/hazardousdrugs/index.htm	th skin or mucous membranes of the powder contained in mycophenolate mofetil capsules. Follow applicable special handling and disposal



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

Version 2024	FOR DESIGNATED DROP SHIP PRODUCT ONLY - if r	ot a designated drop ship, do not complete.	
Order Method for Des	signated Drop Ship Product	Standard Order Receipt and Processing	
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name Phone Expedited Freight Charges o		Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Da Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing	ays
Expedited freight fees billed with each order:		Overnight receipt available:	
Drop Ship service fee billed with each order:		PO Receipt cut off time:	
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday	
Comments:	s only:	Days of week overnight is available: Tuesday Tuesday Wednessi Priority Overnight receipt available: Friday PO Receipt Cut off time: PO Receipt Cut off time: Order receipt method: Phone: Fax: Fax: EDI: Policitie Overnight Fees apply: Tuesday	/ day
Other Data Informati	ion Required to Process PO:	Return Instructions	
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?	
Miscell	aneous Notes:		
		ADDITIONAL INFORMATION	
		Is product order for scheduled patient procedure? Is product order for restocking purposes?	