



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

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Version 2021

Introduction Type:

New Item

Final Version

Date:

9/5/2026

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Novadoz Pharmaceuticals, LLC Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 208559 Medical Device Class, if applicable: DUNS: 08-110-9687 Proprietary Name (if Applicable) and Established Name: Fingolimod Capsules 0.5mg x 30 Selling Unit NDC: 72205-227-30 UDI Description: Size "3" hard gelatin capsules having a white opaque cap imprinting " 0.5 mg" and white opaque body imprinting "MF" with black ink, filled with white to off white colored fine powder Active Ingredient(s): Fingolimod hydrochloride USP URL for Additional Product Information: Address: 20 Duke Road City: Piscataway Key Contact: Phone Number: 908-360-1500 Product Therapeutic Classification:				Application: ANDA UPC: 372205227309 CVX Code: MXV Code: Address 2: Suite A State: NJ Zip: 08854 Email: Sales@novadozpharma.com Fax: 678-608-3778			
Additional Product Information				PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device? No if yes, enter class # a product kit? No if yes, list NDCs of component parts reverse numbered? No co-licensed? No latex-free? Yes preservative-free? Yes correctional institution block? No opioid? No Cannabinoid? No If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here: 72205-227-30		Is the Product... Is the Product... Orphan Drug Status FDA Approval Status Allergens Present Country of Origin India Is this product covered under the Trade Agreements Act (TAA)? No		Size: 30's Strength: 0.5 mg Dosage Form: Capsules Product Shape: Capsule shaped Product Color: White to off white Product Imprint: White opaque cap imprinting "0.5 mg"			
FOR GENERIC DRUG PRODUCTS				PHARMACY ORDER / BILL UNIT			
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Gilenya Authorized Generic *If Authorized Generic, other section fields are not applicable				Rec. sell unit to customer? (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: x Each Gram Milliliter			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				ITEM AND PACKING INFORMATION			
Does supplier meet DSCSA definition of manufacturer? Yes Is product exempt from DSCSA? No If yes, select exemption: Other exemption - Write in: Is product repackaged? No Is product sold by manufacturer's exclusive distributor? No Has FDA granted waiver/exemption/exemption for product? No If yes, attach documentation from FDA.				GLN: 8904159670843 GCP: 89041596 If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product			
GTIN AND HIBCC PRODUCT INFORMATION				COST INFORMATION			
Saleable Unit of Measure Yes Item/Each Yes Box/Carton/Bundle/Inner Pack Yes Case Yes Pallet		Saleable Quantity 24 bottles in case 4,368 bottles in pallet		HIBCC		GTIN-14 00372205227309 30372205227300 50372205227304	
						Unit of Use GTIN-14 00372205227309	
Regular Cost Invoice Cost (WAC) (\$) As of date: 9/5/2026				WHOLESALE USE ONLY: Vendor #: Whsl. Code #: Fineline Code:			

*Please provide any additional information on page 2.

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

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?	☐ 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)			
a. UN/Identification Number	UN0377		
b. Proper Shipping Name	Environmentally hazardous substance, Solid, N.O.S		
c. DOT Hazard Class	9		
d. Packing Group	III		
e. Inhalation Hazard?	☐ No		
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	UN0377		
b. Proper Shipping Name	Environmentally hazardous substance, Solid, N.O.S		
c. DOT Hazard Class	9		
d. Packing Group	III		
e. Inhalation Hazard?	☐ Yes		
Is the product restricted for air shipment? If so, indicate restriction:		☐ No	
☐ Passenger			
☐ Cargo			
☐ Passenger & Cargo			
Is this a reportable quantity? ☐ Yes			
RQ Threshold: 5 litres or less for			
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#			
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:			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

SDS Hazard Classification	
☒ Organic	☐ Corrosive
☐ Inorganic	☐ Oxidizer
☐ Steroid/Androgen	☐ Contact Hazard
Does the product have an Aerosol class? If yes, identify ☐ No	
NFPA Storage Level:	
NFPA Storage Level:	
Is the product a NIOSH hazardous drug? ☐ No	
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 ☐ No	
Comments / Details: (For example, iPledge program?)	
REMS:	
☐ No	
REMS Program Manager Name:	
Supplier Manages REMS registry exclusively:	
Wholesale distributor support:	
Provider Name:	
Site Enrollment Number assigned by Supplier:	
DEA #:	
NCPDP#:	
NPI #:	
Comments	
Registry:	
☐ No	
Registry Program Contact Name:	
Phone:	
Comments	
RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	
Is product returnable for credit:	
URL/Link to returns policy:	
Special regulations or returns requirements for this product in certain states? ☐ No	
If so, which states? Other requirements? Comments?	

Release DATE



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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
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: Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:
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:	
Other Data Information 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?
Miscellaneous Notes:	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?