



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

Version 2024

Introduction Type:  Final Version

Date: 1/14/2026

PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*					
Company Name: Novadoz Pharmaceuticals, LLC			Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.					
Application Number for NDA/ANDA/BLA; PMA/510(k): 220250			NDA 505(b) Type:			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)					
Medical Device Class, if applicable:						Other Temperature Range Requirement (write in)			NA		
DUNS: 081109687						Notes					
Proprietary Name (If Applicable) and Established Name: Eltrombopag Tablets 50mg, 30											
Selling Unit NDC: 72205-158-30			Unit of Use NDC:		UPC: 372205158306						
UDI			CVX Code:		MVX Code:						
Description: Light blue to blue colored, round, biconvex, film coated tablets, debossed with "ME" on one side and "14" on other side, free from physical defects.											
Active Ingredient(s): Eltrombopag Olamine											
URL for Additional Product Information:											
Address: 20 Duke Road			Address 2: Suite A								
City: Piscataway			State: NJ Zip: 08854								
Key Contact:			Email: Sales@novadozpharma.com								
Phone Number: 908-360-1500			Fax:								
Product Therapeutic Classification:											
ADDITIONAL PRODUCT INFORMATION						PRODUCT DESCRIPTION INFORMATION					
The product is?			Is the Product... Direct-Ship Only			Size: 30					
a legend device?			Is the Product... Neither			Strength: 50 mg					
if yes, enter class #			Orphan Drug Status			Dosage Form: Tablets					
a product kit?											
if yes, list NDCs of component parts						Product Shape: round,biconvex					
reverse numbered?						Product Color: Light blue to blue colored					
co-licensed?						Product Imprint: debossed with "ME" on one side and "14" on other side					
latex-free?											
preservative-free?											
correctional institution block?											
opioid?											
Cannabinoid?											
If Unit Dose, is item bar coded to unit dose for hospital scanning?											
If Unit Dose, indicate NDC here: 72205-158-30						Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/>					
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION					
						Unit of Sale <input checked="" type="checkbox"/> Bottle			What is the NDC selling unit? 1 bottle of 30 tablets		
						Box/Carton			(Write-in, e.g. 1 Box of 10 Vials)		
						Ampule			Minimum order quantity? <input type="checkbox"/> Yes		
						Glass					
						Tube					
						Vial Liquid Sgl					
						Vial Liquid Multi					
						Vial Powder Sgl					
						Vial Power Multi					
						Other: Write In					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						PHARMACY ORDER / BILL UNIT					
						Rec. sell unit to customer?			Rx billing unit to pharmacy: <input type="checkbox"/> Each		
						(Write-in, e.g. 1 Vial)			Gram		
						HCPCS J-Code:			Milliliter		
						ITEM AND PACKING INFORMATION					
						Weight Lbs.		Dimensions (US mssmts.)		Volume (Cube)	
						Depth		Width		Height	
Item/Each:		0.072		NA		1.531		3.280		52	
Box/Carton/Bundle/Inner Pack:		NA		NA		NA		NA		NA	
Case:		4.44		10.43		7.28		7.67		582.39	
Pallet:		448.97		47.24		39.37		36.61		68088.698	
						COST INFORMATION					
						Regular Cost			WHOLESALER USE ONLY:		
						Invoice Cost (WAC) (\$)			Vendor #: <input type="checkbox"/>		
						\$700.00			Whs. Code #: <input type="checkbox"/>		
						As of date: 1/14/2026			Fineline Code: <input type="checkbox"/>		
						Signature: <input type="checkbox"/>					
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.											
*Please provide any additional information on page 2.											



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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?
- c. Is the product a CA Prop 65 reproductive toxicant?
- d. Does the product label bear a CA Prop 65 warning?

No

No

No

No

No

No

No

No

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

No

No

No

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?


No

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?


Yes

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

- Passenger
- Cargo
- Passager & Cargo

No

Is this a reportable quantity?  Yes

RQ Threshold:

Is this a marine pollutant?  Yes

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?:

## 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:

## SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen

- Corrosive
- Oxidizer
- Contact Hazard

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

No

NFPA Storage Level:


Is the product a NIOSH hazardous drug?

No

If yes, indicate which:

EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>
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## 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

Limited Distribution Requirement

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

### REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

No

NA

Phone:  NA

No

NA

No

NA

DEA #:  No

NCPDP#:  No

NPI #:  No

Comments:

None

### Registry:

Registry Program Contact Name:  NA

Phone:  NA

Comments:  None

## 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?


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

Release DATE

Version 2024

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

<b>Order Method for Designated Drop Ship Product</b>		<b>Standard Order Receipt and Processing</b>	
<p>Purchase orders may be accepted by:</p> <p>a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only</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: Ships for second day receipt: Ships regular ground for 3-10 days receipt:</p>	
<p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>		<b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b>	
<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="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available: <input type="text"/> Monday <input type="text"/> Tuesday <input type="text"/> Wednesday <input type="text"/> Thursday <input type="text"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Fax: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>	
<b>Class of Trade Restriction:</b>		<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="text"/></p> <p>Comments: <input type="text"/></p>	
<b>Other Data Information Required to Process PO:</b>		<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>	
<b>Miscellaneous Notes:</b>		<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="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>	
<b>Return Instructions</b>			
<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>			
<b>ADDITIONAL INFORMATION</b>			