

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 75mg, 30			Unit of Use NDC: 72205159303			Is this product to be shipped to customers on ice?					
Selling Unit NDC: 72205-159-30			UPC: 372205159303			Is this product to be shipped to customers on dry ice?			No		
UDI			CVX Code: MVX Code:						No		
Description: Brown colored, round shaped, biconvex, film coated tablets, debossed with "ME" on one side and "15" 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? a legend device? <input type="checkbox"/> No			Is the Product... Direct-Ship Only <input type="checkbox"/>			Size: 30					
if yes, enter class # a product kit? <input type="checkbox"/> No			Is the Product... Neither <input type="checkbox"/>			Strength: 75 mg					
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No			Orphan Drug Status <input type="checkbox"/>			Dosage Form: Tablets					
co-licensed? <input type="checkbox"/> No			FDA Approval Status <input type="checkbox"/>			Product Shape: round shaped, biconvex					
Latex-free? <input type="checkbox"/> No			Allergens Present <input type="checkbox"/>			Product Color: Brown colored					
preservative-free? <input type="checkbox"/> Yes			Country of Origin <input type="checkbox"/> India			Product Imprint: debossed with "ME" on one side and "15" on other side					
correctional institution block? <input type="checkbox"/> Yes			Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No								
opioid? <input type="checkbox"/> No											
Cannabinoid? <input type="checkbox"/> No											
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No											
If Unit Dose, indicate NDC here: 72205-159-30											
FOR GENERIC DRUG PRODUCTS											
I. Orange Book Rating: AB						Authorized Generic <input type="checkbox"/>			*If Authorized Generic, other section fields are not applicable		
II. Generic Equivalent to What Brand?: <input type="checkbox"/>											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION											
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes			GLN: 8904159670843								
Is product exempt from DSCSA? <input type="checkbox"/> No			GCP: 89041596								
If yes, select exemption: Other exemption - Write in: <input type="checkbox"/>						If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Is product repackaged? <input type="checkbox"/> No						Provide source manufacturer for repackaged product <input type="checkbox"/>					
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No											
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No											
If yes, attach documentation from FDA. <input type="checkbox"/> No											
GTIN AND HIBCC PRODUCT INFORMATION											
Saleable Unit of Measure		RFID tag(Y/N)		Saleable Quantity		HIBCC		GTIN-14		Unit of Use GTIN-14	
Yes	Item/Each			Bottle of 30 tablets				00372205159303		00372205159303	
NA	Box/Carton/Bundle/Inner Pack			NA				NA		NA	
Yes	Case			48 Bottles in Case				30372205159304			
Yes	Pallet			4416 Bottles in Pallet				50372205159308			
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: <input type="text"/>											

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:

\*Please provide any additional information on page 2.



# 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?
- 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)

Yes

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:

## Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

## REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?  
Website URL:

- No
- No
- NA

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
- No
- No
- NA
- None

Phone:   
DEA #:   
NCPDP#:   
NPI #:

Comments:

None

### Registry:

Registry Program Contact Name:   
Comments:

- No
- NA
- Phone: NA

## 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>PO Receipt Cut off time: <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>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>Miscellaneous Notes:</b>		<b>Return Instructions</b>	
<b>ADDITIONAL INFORMATION</b>		<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>	