



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

Version 2024

Introduction Type: New Item

x Final Version

Date: 1/14/2026

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Novadoz Pharmaceuticals, LLC				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 220250				NDA 505(b) Type:			
Medical Device Class, if applicable:							
DUNS: 081109687							
Proprietary Name (If Applicable) and Established Name: Eltrombopag Tablets 75mg, 30							
Selling Unit NDC: 72205-159-30				Unit of Use NDC:			
UDI				UPC: 372205159303			
CVX Code:				MVX Code:			
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			
Key Contact:				Zip: 08854			
Phone Number: 908-360-1500				Email: Sales@novadozpharma.com			
Fax:							
Product Therapeutic Classification:							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?				Is the Product...			
a legend device? No				Direct-Ship Only Neither			
if yes, enter class #				Orphan Drug Status			
a product kit? No				FDA Approval Status			
if yes, list NDCs of component parts				Allergens Present			
reverse numbered? No				Country of Origin India			
co-licensed? No				Is this product covered under the Trade Agreements Act (TAA)? No			
latex-free? Yes							
preservative-free? Yes							
corrective 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: 72205-159-30							
PRODUCT DESCRIPTION INFORMATION							
Size: 30							
Strength: 75 mg							
Dosage Form: Tablets							
Product Shape: round shaped ,biconvex							
Product Color: Brown colored							
Product Imprint: debossed with "ME" on one side and "15" on other side							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB							
II. Generic Equivalent to What Brand?:							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) 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/exception/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							
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							
Yes Case 48 Bottles in Case 30372205159304							
Yes Pallet 4416 Bottles in Pallet 50372205159308							
ITEM AND PACKING INFORMATION							
Weight Lbs. Dimensions (US msmts.) Volume (Cube) Saleable # Pieces							
Depth Width Height							
Item/Each: 0.080 NA 1.531 3.280 52 1							
Box/Carton/Bundle/Inner Pack: NA NA NA NA NA NA							
Case: 4.86 10.43 7.28 7.67 582.39 48							
Pallet: 487.26 47.24 39.37 36.61 68088.698 4,416							
COST INFORMATION WHOLESALE USE ONLY:							
Regular Cost Invoice Cost (WAC) (\$) Vendor #: Whsl. Code #: Fineline Code:							
As of date: 1/14/2026							

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:



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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?

No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

No

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?

c. Contact Hazard?

No

d. Does this product require special clean-up instructions?

No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

No

Is this product regulated for shipment by DOT?

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?

No

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?

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? ☐ 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:

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?

No

Website URL:

Med Guide Required

Limited Distribution Requirement

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

REMS:

No

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

No

Wholesale distributor support:

No

Provider Name:

DEA #:

Site Enrollment Number assigned

NCPDP#:

by Supplier:

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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</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: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <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>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p>Other Data Information Required to Process PO:</p> <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>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></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>
<p>Miscellaneous Notes:</p> <p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>