



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

Version 2024

Introduction Type: ☒ Final VersionDate:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																					
Company Name: Novadoz Pharmaceuticals, LLC Application: ANDA Application Number for NDA/ANDA/BLA; PMA/510(k): 208596 NDA 505(b) Type: Medical Device Class, if applicable: DUNS: 081109687 Proprietary Name (If Applicable) and Established Name: Ticagrelor Tablets 90mg, 60 Selling Unit NDC: 72205-368-60 Unit of Use NDC: UPC: 372205368606 UDI CVX Code: MVX Code: Description: Yellow, round, biconvex, film coated tablets, debossed with 'M' on one side and '90' on other side Active Ingredient(s): Ticagrelor URL for Additional Product Information: Address: 20 Duke Road City: Piscataway State: NJ Address 2: Suite A Key Contact: Email: sales@novadozpharma.com Zip: 08854 Phone Number: 908-360-1500 Fax: 732-902-2113 Product Therapeutic Classification:				a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F) Other Temperature Range Requirement (write in) Notes Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No b. Contact for temperature excursion questions: Name: Purushotham Kasula Number: +91 9515665918 Group E-mail: purushotham.kasula@msnlab.com c. Special regulations for product in any states? Special returns requirements for this product? No d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? e. Shelf life: Initial shelf life at launch (if different): 48 Months Months 48 Months Months																																					
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? 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? No If Unit Dose, indicate NDC here: 72205-368-60		Is the Product... Is the Product... Direct-Ship Only Orphan Drug Status Neither FDA Approval Status Allergens Present NA Country of Origin India Is this product covered under the Trade Agreements Act (TAA)?		Size: 60 Strength: 90 mg Dosage Form: Tablets Product Shape: Round and biconvex Product Color: Yellow Product Imprint: Debossed with 'M' on one side and '90' on other																																					
FOR GENERIC DRUG PRODUCTS																																									
I. Orange Book Rating: AB ☐ Authorized Generic *If Authorized Generic, other section fields are not applicable 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 <table border="1" style="width:100%;"><tr><td>Yes</td><td>Item/Each</td><td>1 Bottle of 60 Tablets</td></tr><tr><td>NA</td><td>Box/ Carton/ Bundle/ Inner Pack</td><td>NA</td></tr><tr><td>Yes</td><td>Case</td><td>96 Bottles in Case</td></tr><tr><td>Yes</td><td>Pallet</td><td>3168 Bottles in Pallet</td></tr></table>		Yes	Item/Each	1 Bottle of 60 Tablets	NA	Box/ Carton/ Bundle/ Inner Pack	NA	Yes	Case	96 Bottles in Case	Yes	Pallet	3168 Bottles in Pallet	HIBCC <table border="1" style="width:100%;"><tr><td>00372205368606</td></tr><tr><td>NA</td></tr><tr><td>30372205368607</td></tr><tr><td>50372205368601</td></tr></table>		00372205368606	NA	30372205368607	50372205368601																						
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ITEM AND PACKING INFORMATION																																									
<table border="1" style="width:100%;"><thead><tr><th rowspan="2">Item/Each:</th><th rowspan="2">Weight Lbs.</th><th colspan="3">Dimensions (US msmts.)</th><th rowspan="2">Volume (Cube)</th><th rowspan="2">Saleable # Pieces</th></tr><tr><th>Depth</th><th>Width</th><th>Height</th></tr></thead><tbody><tr><td>Box/ Carton/ Bundle/ Inner Pack:</td><td>0.115</td><td>NA</td><td>1.60</td><td>3.90</td><td>73</td><td>1</td></tr><tr><td>Case:</td><td>NA</td><td>NA</td><td>NA</td><td>NA</td><td>NA</td><td>NA</td></tr><tr><td>Pallet:</td><td>12.14</td><td>13.50</td><td>10.43</td><td>9.17</td><td>1291.18</td><td>96</td></tr><tr><td></td><td>440.43</td><td>47.24</td><td>39.37</td><td>35.23</td><td>65522</td><td>3,168</td></tr></tbody></table>		Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	Depth	Width	Height	Box/ Carton/ Bundle/ Inner Pack:	0.115	NA	1.60	3.90	73	1	Case:	NA	NA	NA	NA	NA	NA	Pallet:	12.14	13.50	10.43	9.17	1291.18	96		440.43	47.24	39.37	35.23	65522	3,168		
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COST INFORMATION																																									
Regular Cost Invoice Cost (WAC) (\$) \$23.24 As of date: 5/1/2025		WHOLESALE USE ONLY: Vendor #: Whsl. Code #: Fineline Code:																																							

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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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
- 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? ☐ No

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

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

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
- ☐ 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)
- 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:

SDS Hazard Classification

- ☐ Organic ☒ Corrosive
- ☐ Inorganic ☒ Oxidizer
- ☐ Steroid/Androgen ☒ 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?
If yes, indicate which:

☐ No

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:

Phone:

Supplier Manages REMS registry exclusively: ☐

Wholesale distributor support: ☐

Provider Name:

DEA #:

Site Enrollment Number assigned
by Supplier:

NCPDP#:

NPI #:

Comments

Registry:

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?

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
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: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing 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: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions 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? ☐