



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

Version 2024

Introduction Type: New Item☒ Final VersionDate: 4/2/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text"/> Camber Pharmaceuticals, Inc. Application: <input type="text"/> ANDA				a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA; PMA/510(k): <input type="text"/> 216620 NDA 505(b) Type: <input type="text"/> NOT APPLICABLE				Temperature Range <input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F)			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement <input type="text"/> Excursions permitted to 15°C to 30°C (59°F to 86°F)			
DUNS: <input type="text"/> 11-856-3719				Notes <input type="text"/> Reconstituted liquid can be stored at room temperature up to 30 minutes - then discard.			
Proprietary Name (If Applicable) and Established Name: <input type="text"/> Eltrombopag for Oral Suspension 12.5 mg				Is this product to be shipped to customers on ice? <input type="text"/> No			
Selling Unit NDC: <input type="text"/> 31722-300-32 Unit of Use NDC: <input type="text"/> UPC: <input type="text"/> 331722300322				Is this product to be shipped to customers on dry ice? <input type="text"/> No			
UDI <input type="text"/> CVX Code: <input type="text"/> MXV Code: <input type="text"/>				b. Contact for temperature excursion questions:			
Description: <input type="text"/> Eltrombopag for Oral Suspension 12.5 mg				Name: <input type="text"/> Soma Raju			
Active Ingredient(s): <input type="text"/> Eltrombopag olamine				Number: <input type="text"/> 732-529-0423			
URL for Additional Product Information: <input type="text"/> www.camberpharma.com				Group E-mail: <input type="text"/> somaraju@heterousa.com			
Address: <input type="text"/> 800 Centennial Ave, Suite 1 Address 2: <input type="text"/>				c. Special regulations for product in any states?			
City: <input type="text"/> Piscataway State: <input type="text"/> NJ Zip: <input type="text"/> 08854				Special returns requirements for this product? <input type="text"/> No			
Key Contact: <input type="text"/> Customer Service Email: <input type="text"/> customerservice@camberpharma.com				d. Store product (unit of sale) upright? <input type="text"/> No			
Phone Number: <input type="text"/> 1-866-827-3647 Fax: <input type="text"/> 732-562-8788				Protect product (unit of sale) from light? <input type="text"/> No			
Product Therapeutic Classification: <input type="text"/> Thrombopoietin receptor agonist				e. Shelf life:			
				Initial shelf life at launch (if different): <input type="text"/> Months <input type="text"/>			
				Months <input type="text"/>			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:			
a legend device? <input type="text"/> No		Is the Product... <input type="text"/> Direct-Ship Only		Strength:			
if yes, enter class # <input type="text"/>		Orphan Drug Status <input type="text"/>		Dosage Form:			
a product kit? <input type="text"/> No		FDA Approval Status <input type="text"/>		Product Shape:			
if yes, list NDCs of component parts <input type="text"/>		Allergens Present <input type="text"/> Sugar, Wheat		Product Color:			
reverse numbered? <input type="text"/> No		Country of Origin <input type="text"/> India		Product Imprint:			
co-licensed? <input type="text"/> No		Is this product covered under the <input type="text"/>					
latex-free? <input type="text"/> Yes		Trade Agreements Act (TAA)? <input type="text"/> No					
preservative-free? <input type="text"/> Yes							
correctional institution block? <input type="text"/> No							
opioid? <input type="text"/> No							
Cannabinoid? <input type="text"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> Yes							
If Unit Dose, indicate NDC here: <input type="text"/> 31722-300-12							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text"/> AB Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable							
II. Generic Equivalent to What Brand?: <input type="text"/> Promacta							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text"/> Yes				GLN: <input type="text"/> 00331722498975			
Is product exempt from DSCSA? <input type="text"/> No				GCP: <input type="text"/>			
If yes, select exemption: <input type="text"/>				If yes, was original product purchased <input type="text"/>			
Other exemption - Write in: <input type="text"/>				direct from mfr? <input type="text"/>			
Is product repackaged? <input type="text"/> No				Provide source manufacturer for repackaged product <input type="text"/>			
Is product sold by manufacturer's exclusive distributor? <input type="text"/> Yes							
Has FDA granted waiver/exception/exemption for product? <input type="text"/> No							
If yes, attach documentation from FDA. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<input type="text"/> N	<input type="text"/> 1	<input type="text"/>	<input type="text"/> 00331722300322	<input type="text"/>	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input checked="" type="checkbox"/> Case		<input type="text"/> N	<input type="text"/> 2	<input type="text"/>	<input type="text"/> 20331722300326	<input type="text"/>	
<input type="checkbox"/> Pallet		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost <input type="text"/>				Vendor #: <input type="text"/>			
Invoice Cost (WAC) (\$) <input type="text"/> \$6,169.62				Whsl. Code #: <input type="text"/>			
As of date: <input type="text"/> 5/14/2025				Fineline Code: <input type="text"/>			
*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: <input type="text"/>							



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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?	<input type="checkbox"/>	No	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/>	No	
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/>	No	
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/>	No	
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/>	No	
c. Contact Hazard?	<input type="checkbox"/>	No	
d. Does this product require special clean-up instructions?	<input type="checkbox"/>	No	
(If yes, attach SDS with special instructions.)			
e. Does the product contain DEHP?	<input type="checkbox"/>	No	
Is this product regulated for shipment by DOT?		<input type="checkbox"/> 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?	<input type="checkbox"/>		
Is this product regulated for shipment by IATA?		<input type="checkbox"/> 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?	<input type="checkbox"/>		
Is the product restricted for air shipment? If so, indicate restriction:		<input type="checkbox"/> No	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
Is this a reportable quantity?	<input type="checkbox"/> No		
RQ Threshold:			
Is this a marine pollutant?	<input type="checkbox"/> No		
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
<input type="checkbox"/> No	(if yes, identify method below)		
<input type="checkbox"/> Limited Quantity			
<input type="checkbox"/> Consumer Commodity, ORM-D			
<input type="checkbox"/> Small Quantity (49 CFR 173.4)			
<input type="checkbox"/> Special Permit; DOT-SP			
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP#			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	
Schedule No.	<input type="checkbox"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	<input type="checkbox"/> Yes		
Restricted to retail pharmacy only:	<input type="checkbox"/> No		
Restricted to hospital, clinics, and physician offices only:	<input type="checkbox"/> No		
Restricted from US territories? (explain in comments)	<input type="checkbox"/> No		
Comments:			
SDS Hazard Classification			
<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive		
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer		
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard		
Does the product have an Aerosol class? If yes, identify		<input type="checkbox"/> No	
NFPA Storage Level:			
NFPA Storage Level:			
Is the product a NIOSH hazardous drug?		<input type="checkbox"/> 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?		<input type="checkbox"/> No	
If Yes, is it managed with a pharmacy registry?			
Website URL:			
Med Guide Required		<input type="checkbox"/> No	
Limited Distribution Requirement			
Comments / Details: (For example, iPledge program?)			
REMS:		<input type="checkbox"/> No	
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:		<input type="checkbox"/> No	
Registry Program Contact Name:		Phone:	
Comments			
RETURN INSTRUCTIONS			
Contact tel. # if product received damaged:		1-866-827-3647	
Is product returnable for credit:		<input type="checkbox"/> Yes	
URL/Link to returns policy:		contact - customerservice@camberpharma.com	
Special regulations or returns requirements for this product in certain states?		<input type="checkbox"/> No	
If so, which states? Other requirements? Comments?			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			
Product is co-packaged in a kit with a 40 cc reconstitution vessel, a threaded closure with syringe-port capability, and 30 single use oral dosing syringes.			

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>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<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 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>
Class of Trade Restriction:	
<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>	
Other Data Information Required to Process PO:	Return Instructions
<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>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>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	<p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>