

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

Version 2024						Introduction 1	ype: New Iter	m		x Final Version			Date:	5/6/	2025
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						١	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	IDA/BLA; PMA/510	0(k): 2	16620			NDA 505(b) Type:	NOT APPLICAB	LE		emperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applica	ble:														
DUNS:	11-856-3719								C	ther Temperature Range F	Requirement	Excursions p	ermitted to 1	5°C to 30°C (	(59°F to
Proprietary Name (If Applicable) a		lame: E	Itrombopag for Oral Suspension 1	12.5 mg						(write in)		86°F			
Selling Unit NDC:	31722-300-32		Unit of Use NDC:			UPC:	331722300322		N	otes		Reconstitute			
UDI			CVX Code:			MVX Code:						temperature	up to 30 mini		scard.
Description:	Eltrombopag for	Oral Suspension	12.5 mg							this product to be shipped				No	
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Eltrombopag olamine b. Contact for temperature excursion questions:															
URL for Additional Product Inform	nation:	www.camberph	narma.com							ame:		Soma Raju			
Address:	800 Centennial A	Ave, Suite 1				Address 2:			N	umber:		732-529-042	:3		
City:	Piscataway				State:	NJ	Zip: 08854		Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service	e			Email:		<u>@camberpharma.com</u>								1
Phone Number:	1-866-827-3647				Fax:	732-562-8788				ations for product in any				No	-
Product Therapeutic Classificatio	n:	Thrombopoieti	n receptor agonist						S	pecial returns requirement	s for this product?			No	
	ADDIT	IONAL REODUC	T INFORMATION			PRODUCT	DESCRIPTION INFORMA	TION	d Store produc	(unit of sale) upright?				No	1
The mundoust is 2	ADDIT	TONAL PRODUC		Direct Chir C	)ply	PRODUCTI	SECRIF HON INFORMA	HON			la) from U-1-40				1
The product is? a legend device?		No	Is the Product Is the Product	Direct-Ship C Unit Dose	niy		30 unit-dose pack	rata	e. Shelf life:	rotect product (unit of sa	le) from light?			No 24	Months
if yes, enter class #		NO	Orphan Drug Status	Offit Dose		Size:	30 unit-dose pack	tets		itial shelf life at launch (i	if different):			24	Months
a product kit?		No	Orphan Drug Status				12.5 mg		"	iluai sileli ille at laulicii (i	ii dillerentj.				Wortins
if yes, list NDCs of		1	FDA Approval Status			Strength:					ORDER INFORM	MATION			
component parts			••			Dosage Forr	Powder for oral								
reverse numbered?		No	-			Dosage For	suspension		U	nit of Sale			NDC selling		
co-licensed?		No	Allergens Present							Bottle		1 Box of 30 L			
latex-free?		Yes	Sugar	, Wheat		Product Sha	pe: N/A		_	x Box/Carton		(Write-in, e.	g. 1 Box of 10	) Vials)	
preservative-free? correctional institution block?		Yes	_				Reddish brown to	vollow		Ampule Glass		Minimum o	der quantity	2	Yes
opioid?		No				Product Cole	or:	yellow	-	Tube		William O	uer quantity	ſ	res
Cannabinoid?		No	Country of Origin	India			N/A			Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		,g			Product Imp	rint:			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?		Yes	Is this product covered u							Vial Powder Sgl			Each	-	
If Unit Dose, indicate NDC here:		31722-300-12	Trade Agreements Act (1	ΓAA)?	No					Vial Powder Multi			Inner/Carton	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
					Au	thorized Generic	*If Authorized Generic, o	ther		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not app		Rec. sell unit to				nit to pharma	cv.	
II. Generic Equivalent to What Bra		Promacta							The contract of the contract o		1	TOX DITTING U	Each	.cy.	
						(Write-in, e.g. 1 Vial) Gram									
		DRUG SI	JPPLY CHAIN SECURITY ACT (	DSCSA) INFOR	RMATION				HCPCS J-Code:		1		Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	ıror?	Yes	_	GLN:	0331722498975				ITEN	AND PACKING I	NEORMATIO	N .		
Is product exempt from DSCSA?	ition of manufactu	ilei:	No	-	OLIV.	0331722490973				115.	ANDIAGNING	II ORMATIO	•		
If yes, select exemption:					GCP:						Dimonsi	ons (US msn	nts )	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product pur	chased		Item/Each:	1.6	10.75	6	5.25	338.63	1
Is product sold by manufacturer's			Yes		direct from m						10.75	U	5.25	330.03	,
Has FDA granted waiver/exception If yes, attach documentation fro		product?	No		Provide sour	ce manufacturer fo	r repackaged product		Box/Carton/Bun Inner Pack:	dle/					
if yes, attach documentation fro	m FDA.								Case:						
			GTIN AND HIBCC PRODUCT II	NFORMATION					Case.	4	13	11.5	6	897	2
									Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTI	N-14							
II		Quantity			200	0470000000									
x Item/Each Box/Carton/Bundle/Inner Pack	N	1			003	31722300322				COST INFORMATION			WHOLESALE	R USE ON	γ.
X Case	N	2			203	31722300326	-			Joon IIII OMINATION				- OOL ONL	
Pallet							1		Regular Cost			Vendor #:			
									Invoice Cost (W	AC) (\$)	\$6,169.62	Whsl. Code			
												Fineline Co	de:		
							-		As of date:	5/14/2025					
			Attach copy of SAFETY DA	TA SHEET (SE	S) or non haza	ard letter PACKAGE	INSERT LAREL AND PH	HOTO OF P	PRODUCT PACKAG	NG and BARCODE		L			
İ	formation on nage	_	,				Designated Drop Ship O								



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

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	il yes, illulcate willon.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group	- Hazardodo Waste Identinication						
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
	I Table Ordinate India						
Is this product regulated for shipment by IATA?  No	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS)	REMS OF REGISTRY RESTRICTIONS						
a. UN/Identification Number	LU DEMO UL LU						
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group e. Inhalation Hazard?	Website URL:						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)							
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ARRIVATORAGE INFORMATION	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No							
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  No	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:	product in certain states?						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANE	OUS 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 cap							
The reduction to the paragraph and with a 40 to reconstitution vesser, a unequed closure with syninge-port cap	ability, and obtaining assuming asymmetra.						



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

#### Version 2024

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

Purchase order ally receipt cut off time by supplier  a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing					
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier					
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No.  Expedited freight Charges or Other Designated Drop Ship Fees:  Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:					
d. Phone only e. Suppler Web Site only Site Address:  Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Days of week overnight for ceipt: Days of week overnight for ships for ceipt files: Days of week overnight for ships for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days								
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL. company / contact #: Name: Phone:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees bi			Shipping lead time of PO: Hours Days					
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