

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

				Introduction Type:	New Item		x Final Version			Date:	4/2/	2025
		PRODUCT INFORMATIO	DN .				SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceuticals, Inc.			Application:	ANDA	a. Temperature	- Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN		206788		NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical						T						
DUNS:	11-856-3719					c	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	nd Established Name:	Eltrombopag Tablets 75 mg				T	(write in)					
Selling Unit NDC:	31722-844-30	Unit of Use NDC:	31722-844-30		722844307	N	Notes					
UDI		CVX Code:		MVX Code:								
Description:	Eltrombopag Tablets 75 mg					ls	s this product to be shippe	d to customers on i	ce?		No	1
						ls	s this product to be shippe	d to customers on o	dry ice?		No	
Active Ingredient(s):	Eltrombopag	g olamine										
		and a second second					emperature excursion qu	estions:	O Dain			
URL for Additional Product Inform Address:	800 Centennial Ave, Suite 1	rpharma.com		Address 2:			Name:		Soma Raju 732-529-042	22		
City:	Piscataway		State:		08854		Number: Group E-mail:			io neterousa.cor	n	
Key Contact:	Customer Service		Email:	customerservice@carr					Jonnaraja en	101010434.001	<u>u</u>	
Phone Number:	1-866-827-3647		Fax:	732-562-8788		c. Special regul	lations for product in any	states?			No	1
Product Therapeutic Classificatio	n: Thrombopo	etin receptor agonist				s	Special returns requiremen	ts for this product?			No	
						-						1
	ADDITIONAL PROD	UCT INFORMATION		PRODUCT DESC	RIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	1
The product is?		Is the Product	Direct-Ship Only				Protect product (unit of sa	ale) from light?			No	1
a legend device?	No		Unit of Use		30 ct	e. Shelf life:	roteet product (unit of s	ic) nom ngne.			36	Months
if yes, enter class #		Orphan Drug Status		Size:			nitial shelf life at launch (if different):				Months
a product kit?	No			Strength:	75 mg			-				1
if yes, list NDCs of		FDA Approval Status		Su'engui.				ORDER INFOR	IATION			
component parts				Dosage Form:	Film-coated tablet							
reverse numbered?	No	_		Decagerentin		<u> </u>	Jnit of Sale			NDC selling	unit?	
co-licensed?	No	Allergens Present			Devel block barrel		x Bottle		1 Bottle of 3		0 \ (- 1 -)	
latex-free?	Yes	Dye, Wh	neat	Product Shape:	Round, biconvex, bevel edged		Box/Carton		(vvrite-in, e	g. 1 Box of 1	J Viais)	
preservative-free? correctional institution block?	Yes				Off white to light yellow		Ampule Glass		Minimum o	der quantity	2	Yes
opioid?	No			Product Color:	On white to light yellow	-	Tube		Winning	uer quantity	•	163
Cannabinoid?	No	Country of Origin	India		Debossed with 'H' on one side and	-	Vial Liquid Sgl					
If Unit Dose, is item bar coded to u				Product Imprint:	'E13' on the other side		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?		Is this product covered under	er the				Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA	A)? No				Vial Powder Multi			Inner/Cartor	/Pack	
							Other: Write In			Case		
		FOR GENERIC DRUG PROD										
		TOR GENERIC DRUGTROD	OUCTS									
		TOK GENERIC DRUG PROD										
					uthorized Generic, other			IARMACY ORDER				
I. Orange Book Rating:	AB				uthorized Generic, other ion fields are not applicable	Rec. sell unit to		IARMACY ORDER		nit to pharm	acy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra							o customer?	IARMACY ORDER		Each	acy:	
	nd?: Promacta		Au			(Write-in, e.g. 1	vial)	IARMACY ORDER		Each Gram	acy:	
	nd?: Promacta	SUPPLY CHAIN SECURITY ACT (DS	Au				vial)	IARMACY ORDER		Each	acy:	
II. Generic Equivalent to What Bra	nd?: Promacta	SUPPLY CHAIN SECURITY ACT (DS	CSA) INFORMATION	sect		(Write-in, e.g. 1	Vial)]	Rx billing u	Each Gram Milliliter	acy:	
	nd?: Promacta		Au			(Write-in, e.g. 1	Vial)	IARMACY ORDER	Rx billing u	Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?	nd?: Promacta	SUPPLY CHAIN SECURITY ACT (DS	CSA) INFORMATION GLN:	sect		(Write-in, e.g. 1	o customer? Vial) : ITEN	AND PACKING I	Rx billing u	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	nd?: Promacta	SUPPLY CHAIN SECURITY ACT (DS	CSA) INFORMATION	sect		(Write-in, e.g. 1	Vial)	AND PACKING I	Rx billing u	Each Gram Milliliter N	Volume	Saleable # Pieces
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?: Promacta	SUPPLY CHAIN SECURITY ACT (DS	CSA) INFORMATION GLN: GCP:	0331722498975	ion fields are not applicable	(Write-in, e.g. 1 HCPCS J-Code:	v customer? Vial) : ITEN Weight Lbs.	I AND PACKING I Dimens Depth	Rx billing u	Each Gram Milliliter N nts.) Height	Volume (Cube)	Pieces
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	IND Promacta DRUG	SUPPLY CHAIN SECURITY ACT (DS Yes No No Yes	CSA) INFORMATION GLN: GCP:	0331722498975	ion fields are not applicable	(Write-in, e.g. 1	o customer? Vial) : ITEN	AND PACKING I	Rx billing u	Each Gram Milliliter N	Volume	
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HDA Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024 For Designa	ted Drop Ship Only Products, Please Use Page 3
MATERIAL HA	ZARD 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? Does the product label bear a CA Prop 65 warning? 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? Is this product regulated for shipment by DOT? No	x 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: Image: Contact Hazard
(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?	Is the product a NIOSH hazardous drug? If yes, indicate which: Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
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?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? No Website URL: Image: Colored and Col
Is the product restricted for air shipment? If so, indicate restriction: Passenger No Cargo Passenger & Cargo Is this a reactable quantity? No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) REMS: No
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 Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned DEA #: by Supplier: NPI #:
SP#	Registry: No Registry Program Contact Name: Phone:
ADD'L STORAGE INFORMATION Is the Product Controlled Substance Code	Comments RETURN INSTRUCTIONS
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: No Schedule No. Is it a scheduled listed chemical product?: No	KEI URN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes URL/Link to returns policy: Yes
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 Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



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Version 2024	FOR DESIGNATED DROP SHIP PRODUCT ONLY - if r	ot a designated drop ship, do not complete.	
Order Method for Des	signated 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 Expedited Freight Charges o		Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Da Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing	ays
Expedited freight fees billed with each order:		Overnight receipt available:	
Drop Ship service fee billed with each order:		PO Receipt cut off time:	
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday	
Comments:	s only:	Days of week overnight is available: Tuesday Tuesday Wednessi Priority Overnight receipt available: Friday PO Receipt Cut off time: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Policity	/ day
Other Data Informati	ion Required to Process PO:	Return Instructions	
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?	
Miscell	aneous Notes:		
		ADDITIONAL INFORMATION	
		Is product order for scheduled patient procedure? Is product order for restocking purposes?	