

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

Version 2024						Introduction T	ype: New Ite	em		x Final Version			Date:	5/6/2	2025
	PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*								
Company Name:	Camber Pharmac	ceuticals, Inc.				Applicat	tion: ANDA	A	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	DA/BLA; PMA/510	O(k): 20678	88			NDA 505(b) Type:	NOT APPLICAB	BLE		Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applical	ble:														
DUNS:	11-856-3719									Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Eltron	mbopag Tablets 12.5 mg							(write in)					
Selling Unit NDC:	31722-841-30		Unit of Use NDC:		31722-841-30		331722841306			Notes					
UDI			CVX Code:			MVX Code:			l						
Description:	Eltrombopag Tab	lets 12.5 mg							Ī	Is this product to be shipped	d to customers on i	ce?		No	
										Is this product to be shipped	d to customers on o	try ice?		No	
Active Ingredient(s): Eltrombopag olamine b. Contact for temperature excursion questions:															
URL for Additional Product Inform	antion:	www.camberpharm	na com							temperature excursion qui Name:	estions:	Soma Raju			
Address:	800 Centennial A		na.com		1	Address 2:			l	Number:		732-529-042	23		
City:	Piscataway	,			State:	NJ Zip : 08854				Group E-mail:			neterousa.com	n	
Key Contact:	Customer Service	Э			Email:	customerservice(camberpharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for product in any states?			states?			No	
Product Therapeutic Classificatio	n:	Thrombopoietin re-	ceptor agonist							Special returns requirement	s for this product?			No	
					_				_						
	ADDITI	IONAL PRODUCT IN	NFORMATION			PRODUCT	DESCRIPTION INFORMA	ATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only					Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct		e. Shelf life:					36	Months
if yes, enter class #			Orphan Drug Status							Initial shelf life at launch (if different):				Months
a product kit?		No				Strength:	12.5 mg				ORDER INFORM	AATION			
if yes, list NDCs of component parts			FDA Approval Status				Film-coated table	n#			ORDER INFORM	IATION			
reverse numbered?		No				Dosage Forn	n:	31		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 3			
latex-free?		Yes		Marina		Due due t Che	Round, biconvex	, bevel		Box/Carton		(Write-in, e.	g. 1 Box of 10	0 Vials)	
preservative-free?		Yes	Dye,	Wheat		Product Sha	edged			Ampule					
correctional institution block?		No				Product Cold	Off white			Glass		Minimum o	rder quantity	?	Yes
opioid?		No								Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	rint: Debossed with 'H' on one 'E10' on the other side	e side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		In this product covered u	ndor the						Vial Liquid Multi Vial Powder Sql			many of whi Each	ch package t	type?
If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		No					Vial Powder Sgi Vial Powder Multi			Inner/Carton	/Pack	
III CINE 2000, Indicate (120 noise				, .	.10				Other: Write In Case						
			FOR GENERIC DRUG PR	ODUCTS											
					Au	thorized Generic	*If Authorized Generic, o			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not ap	plicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Bra	ind?:	Promacta						Each							
								(Write-in, e.g.	1 Vial)			Gram			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION HCPCS J-Code: Milliller															
Does supplier meet DSCSA defini	tion of manufactur	ror?	Yes	_	GLN:	0331722498975				ITEN	AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?	tion of manadacta		No	-	OLIV.	0001122430310					.,		•		
If yes, select exemption:					GCP:				i I		Dimone	ons (US msn	nts)	Volume	Saleable #
Other exemption - Write in:					001.				1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	iginal product pure	chased		Item/Each:	0.08		1		5.63	1
Is product sold by manufacturer's	exclusive distribu	utor?	Yes		direct from m					0.08	1.5	1.5	2.5	5.63	1
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	r repackaged product		Box/Carton/Bu	ındle/					
If yes, attach documentation from	m FDA.								Inner Pack:						
		CT	IN AND HIBCC PRODUCT IF	IEODMATION					Case:	2.2	9.75	6.75	4	263.25	24
		GI	IN AND HIBCC PRODUCT II	RECKINATION					Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTII	N-14	Unit of Use GTI	IN-14	l unct.						
	3()	Quantity													
x Item/Each	N	1			003	31722841306	0033172284130	06							
Box/Carton/Bundle/Inner Pack										COST INFORMATION			WHOLESALE	ER USE ONL	Y:
X Case	N	24			203	31722841300	-		II <u>.</u>						
Pallet					-		-		Regular Cost	MAC) (¢)	60 400 00	Vendor #:	4.		
							-		Invoice Cost (MAC) (\$)	\$6,169.62	Whsl. Code Fineline Co			
							-		As of date:	5/14/2025		. IIICIIIIE CO			
							1		11			1			
							_		1 1			1			
			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza	rd letter, PACKAGE	INSERT, LABEL AND PH	HOTO OF P	PRODUCT PACKA	GING and BARCODE.					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	No	SC	S Hazard Classification			
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning?	No No No	x Organic Inorganic Steroid/Androgen	Corrosive Oxidizer Contact Hazard			
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?	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class d. Packing Group		Haza EPA Hazardous Waste Code:	rdous Waste Identification Waste Characteristics			
e. Inhalation Hazard? Is this product regulated for shipment by IATA?	No	EFA Hazardous Waste Code.		Waste Characteristics		
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS			
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?		Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No			
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	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)		REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:	No	Phone: DEA #: NCPDP#: NPI #:		
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments				
SP#		Registry: Registry Program Contact Name:	No	Phone:		
ADD'L STORAGE INFORMATION		Comments		Thoric.		
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	No	RI	ETURN INSTRUCTIONS			
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 Yes			
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 - customerse	rvice@camberpharma.com			
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only:	No No	Special regulations or returns requirements for this product in certain states?				
Restricted from US territories? (explain in comments) Comments:	No	If so, which states? Other requirements? Comments?				
MI	SCELLANEC	US NOTES and/or Image of Product Barcode:				



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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:				
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