

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

Version 2024						Introduction 1	Type: New Item	m] [x Final Version			Date:	5/6/2	2025
	PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name:	Camber Pharmac	ceuticals, Inc.				Applica	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	° – 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 25 mg							(write in)					
Selling Unit NDC:	31722-842-30		Unit of Use NDC:		31722-842-30		331722842303			Notes					
UDI			CVX Code:			MVX Code:									
Description:	Eltrombopag Tabl	lets 25 mg							Ţ	Is this product to be shipped	to customers on i	ce?		No	
										Is this product to be shipped	to customers on o	Iry ice?		No	
Active Ingredient(s): Eltrombopag olamine															
URL for Additional Product Inform	URL for Additional Product Information: www.camberpharma.com								b. Contact for temperature excursion questions: Name: Soma Raju						
Address:	800 Centennial A		iia.com			Address 2:			a l	Name: Number:		732-529-042	3		
City:	Piscataway	iro, ouno i			State:	NJ	Zip: 08854			Group E-mail:			eterousa.con	n	
Key Contact:	Customer Service	9			Email:	customerservice(@camberpharma.com							_	
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regulations for product in any states?					1	
Product Therapeutic Classificatio	n:	Thrombopoietin red	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	le) from light?			No	1
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			Size.				Initial shelf life at launch (if different):				Months
a product kit?		No				Strength:	25 mg								
if yes, list NDCs of			FDA Approval Status								ORDER INFORM	MATION			
component parts reverse numbered?		1.1				Dosage Forn	n: Film-coated table	et		II-14 - 4 O - I-		\A/lag4 := 4lag	NDC selling		
co-licensed?		No	Allergens Present						r	Unit of Sale x Bottle		1 Bottle of 3		unit?	
latex-free?		No Yes					Round, biconvex.	hovel		Box/Carton			g. 1 Box of 10) Viale)	
preservative-free?		Yes	Dye,	Wheat		Product Sha	pe: edged	, bever		Ampule		(**************************************	g. 1 Dox of 10	o viaio)	
correctional institution block?		No				Burnet Oct	Poigo			Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Cole	or:			Tube				'	
Cannabinoid?		No	Country of Origin	India		Product Imp	rint: Debossed with 'H' on one 'E11' on the other side	e side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					Froductilip	E11 on the other side			Vial Liquid Multi				ch package t	type?
hospital scanning?			Is this product covered u							Vial Powder Sgl		1	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	No					Vial Powder Multi			Inner/Carton	/Pack	
									J.	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS											
					Au	thorized Generic	*If Authorized Generic, o	other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			_		anoneou conono	section fields are not app		Rec. sell unit t						
II. Generic Equivalent to What Bra		Promacta							Rx bining unit to customer?						
II. Generic Equivalent to what Brand?.							(Write-in, e.g. 1 Vial)								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Witerin, e.g. 1 'visi) Gilliter HCPCS JCode: Milliter															
Does supplier meet DSCSA defini	tion of manufactur	rer?	Yes		GLN:	0331722498975				ITEN	AND PACKING I	NFORMATIO	l		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msn	•	Volume	Saleable #
Other exemption - Write in:										TTOIGHT EDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		riginal product pur	chased		Item/Each:	0.09	1.5	1.5	2.5	5.63	1
Is product sold by manufacturer's Has FDA granted waiver/exception			Yes No	-	direct from m		r repackaged product		Box/Carton/Bu	indle/					
If yes, attach documentation from		roduct?	140		Provide sour	ce manuracturer ic	г гераскадей ргодист		Inner Pack:	male/					
ii yes, attacii accamentation noi	DA.								Case:						
		GT	IN AND HIBCC PRODUCT II	NFORMATION					1	2.6	9.75	6.75	4	263.25	24
									Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTI	IN-14							
		Quantity													
x Item/Each	N	1			003	31722842303	0033172284230	03		COST INFORMATION			MHOLECAL	R USE ONL	V.
Box/Carton/Bundle/Inner Pack	N	24			202	31722842307				COST INFORMATION			WHOLESALE	ER USE UNL	.1:
X Case Pallet	IN	24			203	01122042301			Regular Cost			Vendor #:			
1 Elliot									Invoice Cost (\	VAC) (\$)	\$6 169 62	Whsl. Code	#:		
											\$0,100.02	Fineline Co			
									As of date:	5/14/2025			1		
									11			Ì			
*Please provide any additional inf			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza		INSERT, LABEL AND PH		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 with each order: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee bil	a. EDI		Cut off time:				
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