

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

Version 2024						Introduction 1	ype: New Item		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. Temp	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	IDA/BLA; PMA/510	O(k): 20678	88			NDA 505(b) Type:	NOT APPLICABLE			erature 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 50 mg							write in)					
Selling Unit NDC:	31722-843-30		Unit of Use NDC:		31722-843-30		331722843300		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Eltrombopag Tab	lets 50 mg								product to be shipped				No	
									Is this	product to be shipped	d to customers on o	ry ice?		No	
Active Ingredient(s): Eltrombopag olamine b. Contact for temperature excursion questions:															
URL for Additional Product Inform	nation:	www.camberpharm	na com					b. Conta	act for tempe :Name		estions:	Soma Raju			
Address:	800 Centennial A		na.com			Address 2:			Numbe			732-529-042	23		
City:	Piscataway				State:	NJ		Group E-mail: somaraju@heterousa.com			n				
Key Contact:	Customer Service	Э			Email:	customerservice(Zip: 08854 Camberpharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for product in any states?				No			
Product Therapeutic Classificatio	n:	Thrombopoietin re-	ceptor agonist						Specia	al returns requirement	s for this product?			No	
	ADDITI	IONAL PRODUCT IN	NFORMATION			PRODUCT	DESCRIPTION INFORMATIO	d. Store	product (uni	t of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only	1				ct product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct	e. Shelf						36	Months
if yes, enter class #			Orphan Drug Status						Initial	shelf life at launch (i	if different):				Months
a product kit?		No				Strength:	50 mg				ORDER INFORM	IATION			
if yes, list NDCs of component parts			FDA Approval Status				Film-coated tablet				ORDER INFORM	IATION			
reverse numbered?		No				Dosage Forn	n:		Unit of	f Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x			1 Bottle of 3			
latex-free?		Yes		NA/lb a a t		Due duet Che	Round, biconvex, bev	el		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 Cole	Off white			Glass		Minimum or	der quantity	?	Yes
opioid?		No								Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	rint: Debossed with 'H' on one side a 'E12' on the other side	nd		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 Sal			many of whi	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				, .					Other: Write In Case						
			FOR GENERIC DRUG PR	ODUCTS											
					Au	thorized Generic	*If Authorized Generic, other			PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applica	Rec. sel	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Promacta							Each								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATIO					ATION			n, e.g. 1 Vial)				Gram			
		DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			HCPCS	J-Code:		1		Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	ror?	Yes	_	GLN:	0331722498975				ITEN	AND PACKING I	FORMATIO	V		
Is product exempt from DSCSA?	ition of manarata		No	-	OLIV.	0001122400010					.,		•		
If yes, select exemption:					GCP:						Dimonei	ons (US msn	nts)	Volume	Saleable #
Other exemption - Write in:					001.					Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product pur	chased	Item/Ea	ch:	0.00					
Is product sold by manufacturer's	exclusive distribu	utor?	Yes		direct from m					0.09	1.5	1.5	2.5	5.63	1
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	r repackaged product		rton/Bundle/						
If yes, attach documentation from	m FDA.							Inner Pa	ack:						
		CT	IN AND HIBCC PRODUCT II	JEODMATION				Case:		2.6	9.75	6.75	4	263.25	24
		GI	IN AND HIBCC PRODUCT II	NFORMATION				Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GTIN-14								
	3(,	Quantity													
x Item/Each	N	1			003	31722843300	00331722843300								
Box/Carton/Bundle/Inner Pack									CC	OST INFORMATION			WHOLESALE	ER USE ONL	.Y:
X Case	N	24			203	31722843304	-								
Pallet					_		-	Regular		· • \	M44 405 07	Vendor #:	ш.		
							-	invoice	Cost (WAC) (Ψ)	\$11,105.07	Whsl. Code Fineline Co			
							-	As of da	ate:	5/14/2025		. momie ou			
							1					1			
			Attach copy of SAFETY DA	TA SHEET (SI	DS) or non haza	rd letter, PACKAGE	INSERT, LABEL AND PHOT	O OF PRODUCT F	PACKAGING a	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 servi	a. EDI		Cut off time:				
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