

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

Version 2021						Introduction Ty	ype:	Post Launch Change		x Final Version			Date:	6/23	3/2024
			PRODUCT INFORMAT	TION						SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 21001						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicable:															
DUNS:	11-856-3719									Other Temperature Range	Requirement				
Proprietary Name (If Applicable) as	nd Established Na	ame: Albe	endazole Tablets, USP 200 mg							(write in)	·				
Selling Unit NDC:	31722-935-02		Unit of Use NDC:		31722-935-02	UPC:	331722935	029		Notes					
UDI			CVX Code:			MVX Code:									
Description: Albendazole Tablets, USP 200 mg Is this product to be shipped to customers on ice? No									1						
•										Is this product to be shippe				No	1
Active Ingredient(s):		Albendazole, US	P												-
							b. Contact for	temperature excursion qu	estions:						
URL for Additional Product Inform		www.camberpha	ma.com							Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:				Number:		732-529-042			
City:	Piscataway  Customer Service				NJ Zip: 08854 customerservice@camberpharma.com				Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>		
Key Contact:	1-866-827-3647	1				732-562-8788			a Special rea	ulations for product in any	ctotoc?			No	7
Phone Number:		Anthelmintic			гах.	132-302-0100			c. Special reg	ulations for product in any					-
Product Therapeutic Classification	1:	Antheiminuc								Special returns requirement	ts for this product?			No	_
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?															
	ADDITIO	ONAL PRODUCT				PRODUCT DI	ESCRIFTIC	DNINFORMATION	a. Store produ						_
The product is?			Is the Product	Direct-Ship (	Only					Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	2 ct		e. Shelf life:					24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				200			Initial shelf life at launch (	if different):				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:	200	ilig			ORDER INFORM	IATION			
component parts			1 DA Approvai Status				Film	coated tablet			ORDER IN OR	IATION			
reverse numbered?		No				Dosage Form:	ı:   · ····	oodiod tablot		Unit of Sale		What is the	NDC sellina	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 2			
latex-free?		Yes				Duadust Chan	Rou	ind, biconvex		Box/Carton		(Write-in, e.		0 Vials)	
preservative-free?		Yes	Dairy,	Lactose		Product Shap	je:			Ampule					
correctional institution block?		No	-			Product Color	whi	te to off-white		Glass		Minimum or	der quantity	?	Yes
opioid?		No				r roduct color				Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri	int: Debo	ssed with 'V32' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for						and p	nail of the other side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u		NI.					Vial Powder Sgl			Each	/DI-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No					Vial Powder Multi Other: Write In			Inner/Carton Case	/Pack	
			FOR GENERIC DRUG PRO	DUCTE						Other. Write in			Case		
			FOR GENERIC DRUG FRO	DUCIS											
					Auth	norized Generic	*If Authoriz	ed Generic, other		PI	IARMACY ORDER	/ BILL UNIT			
	AB			_	7100			ds are not applicable	Rec. sell unit						
I. Orange Book Rating: II. Generic Equivalent to What Brar		Albenza							Rec. sell unit	to customer?		Rx billing ur		acy:	
ii. Generic Equivalent to what Bran	ia ::	Albertza							(Write-in, e.g.	1 Vial)			Each Gram		
		DRUG SUP	PLY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION				(vviito iii, o.g.				Milliliter		
			·	•											
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes	T	GLN:	0331722498975				ITEN	I AND PACKING II	NFORMATION			
Is product exempt from DSCSA?			No							·					
If yes, select exemption:					GCP:						Dimensi	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was orig	ginal product purch	hased		Item/Each:	0.04	1.37	1.37	2	3.8	1
Is product sold by manufacturer's			Yes		direct from mf						1.57	1.57		3.0	
Has FDA granted waiver/exception		oduct?	No		Provide source	e manufacturer for	repackage	ed product	Box/Carton/B	undle/					
If yes, attach documentation from	n FDA.								Inner Pack:						
			TIN AND HIBCC PRODUCT IN	IFORMATION					Case:	1.05	8.75	6.25	2.75	150.4	24
			TIN AND HIBCC PRODUCT IN	IFORMATION					Pallet:						
Saleable Unit of Measure	9	Saleable Quantity	HIBCC		GTIN	-14	He	nit of Use GTIN-14	Pallet:						
X Item/Each	3	1	TIBEC			1722935029		331722935029							
Box/Carton/Bundle/Inner Pack					0000		30			COST INFORMATION			NHOLES <u>AL</u>	ER USE ONL	LY:
X Case		24			2033	1722935023									
Pallet									Regular Cost			Vendor #:			
									Invoice Cost (	WAC) (\$)	\$60.00	Whsl. Code	#:		
										****		Fineline Cod	le:		
									As of date:	4/1/2021					
			Attack conv. of CAFETY D.A	TA CLIEFT (OF	)C) b	James DACKAGE!	INCEDT 1.	ADEL AND DUOTO OF D	DODUCT DACKA	CINC and BARCORE					
		•	Attach copy of SAFETY DA	IA SHEET (SE	or non hazard נכי	l letter, PACKAGE I See new p. 3 for D			RODUCT PACKA	GING and BARCODE. Signature:					
*Please provide any additional info															



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS 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	x     Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     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	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:						
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	Is the product a NIOSH hazardous drug?  If yes, indicate which:						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics						
Is this product regulated for shipment by IATA?	LEATING AUGUS WASTE COUE.						
(if yes, answer a-e below and provide SDS)	REMS or 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:						
Is the product restricted for air shipment? If so, indicate restriction:  Passenger  Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
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:  No  Registry Program Contact Name:  Phone:						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments						
Is the Product							
Controlled Substance?  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  No  Controlled Substance Code  Listed Chemical (List I or II)  No  If yes, indicate which:  Is it a scheduled listed chemical product?:  No	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  Is product returnable for credit:  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 - customerservice@camberpharma.com						
Restricted to retail pharmacy only:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	product in certain states? No If so, which states? Other requirements? Comments?						
Comments:							
MISCELLA	NEOUS 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.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:		Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?