

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

Version 2024						Introduction Type:	New Item	x	Final Version			Date:	6/12/	/2025
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name:	Camber Pharmace	euticals, Inc.				Application:	ANDA	a. Temperature – In	dicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN	IDA/BLA; PMA/510(k): 212278	j			NDA 505(b) Type:	NOT APPLICABLE	Temp	erature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applicat														
DUNS:	11-856-3719								Temperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Atazana	avir Capsules 300 mg	0.1700					(write in)					
Selling Unit NDC:	31722-655-30		Unit of Use NDC: CVX Code:	31/22-	-655-30	UPC: 331 MVX Code:	722655309	Notes	6					
02.			CVX Code:			WIVA Code.								1
Description:	Atazanavir Capsul	es 300 mg							s product to be shippe				No	
Active Ingredient(s): Atazanavir sulfate No														
Active ingrequent(s).														
URL for Additional Product Inform		www.camberpharma	com					Nam	e:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1				Address 2:		Num			732-529-042			
City:	Piscataway				tate:		08854	Grou	p E-mail:		somaraju@h	eterousa.cor	<u>1</u>	
Key Contact: Phone Number:	Customer Service 1-866-827-3647				nail: 'ax:	customerservice@can 732-562-8788	berpharma.com	a Special regulatio	ns for product in any	ctatas?			No	1
Product Therapeutic Classification		Protease inhibitor			ax.	132-302-0100			ial returns requiremen				No	
	41.	1 Totease minibitor						Spec	lai returns requiremen	ts for this product?			NU	
	ADDITIC	ONAL PRODUCT INF				PRODUCT DESC	RIPTION INFORMATION	d. Store product (ur	nit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship Only					ect product (unit of s	ale) from light?			No	i
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct	e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			5126.			I shelf life at launch	(if different):				Months
a product kit?		No				Strength:	300 mg							_
if yes, list NDCs of			FDA Approval Status								NATION			
component parts reverse numbered?		No				Dosage Form:	Hard gelatin capsule	Unit	of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					x			1 Bottle of 3		unit.	
latex-free?		Yes	Dairy, Lactose, Casein,	Whey, Alcohol, Anim	al		Capsule		Box/Carton			q. 1 Box of 10) Vials)	
preservative-free?		Yes	Prod			Product Shape:			Ampule			-		
correctional institution block?		No				Product Color:	Orange opaque cap and		Glass		Minimum or	der quantity	?	Yes
opioid?		No					green opaque body		Tube					
Cannabinoid? If Unit Dose, is item bar coded to u		No	Country of Origin	India		Product Imprint:	Imprinted with 'H' on cap in black color and 'A8' on body in black color		Vial Liquid Sgl Vial Liquid Multi		K Vaa haw			h
hospital scanning?	unit dose for		Is this product covered ur	nder the					Vial Powder Sgl		If Yes, how	Each	chi package	typer
If Unit Dose, indicate NDC here:			Trade Agreements Act (T.						Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS										
				_	Aut		uthorized Generic, other ion fields are not applicable			HARMACY ORDER				
I. Orange Book Rating:	AB	Deverter				360	ion neius are not applicable	Rec. sell unit to cus	stomer?	-	Rx billing u		icy:	
II. Generic Equivalent to What Bra	ind?:	Reyataz						(Write-in, e.g. 1 Vial)			Each Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFORMATIO	N			HCPCS J-Code:)			Milliliter		
				,										
Does supplier meet DSCSA definit	ition of manufacture	er?	Yes	GLN:		0331722498975			ITE	M AND PACKING I	NFORMATIO			
Is product exempt from DSCSA?			No											
If yes, select exemption:				GCP:					Weight Lbs.		ions (US msn		Volume	Saleable #
Other exemption - Write in:								Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product repackaged?												3.3	11.91	1
is product sold by manufacturor's	s exclusive distribut	tor?	No			ginal product purchase	20	item/Each:	0.12	1.9	1.9			
Is product sold by manufacturer's Has FDA granted waiver/exception				direct	from mf	r?		Box/Carton/Bundle		1.9	1.9			
Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from	n/exemption for pro		Yes	direct	from mf					1.9	1.9			
Has FDA granted waiver/exception	n/exemption for pro	oduct?	Yes No	direct Provid	from mf	r?		Box/Carton/Bundle/			1.9	4.5	423	24
Has FDA granted waiver/exception	n/exemption for pro	oduct?	Yes	direct Provid	from mf	r?		Box/Carton/Bundle/ Inner Pack: Case:		1.9 11.75		4.5	423	24
Has FDA granted waiver/exception If yes, attach documentation from	n/exemption for pro m FDA.	oduct?	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc	r? e manufacturer for rep	ackaged product	Box/Carton/Bundle/				4.5	423	24
Has FDA granted waiver/exception	n/exemption for pro	oduct? GTIN Saleable	Yes No	direct Provid	from mf	r? e manufacturer for rep		Box/Carton/Bundle/ Inner Pack: Case:				4.5	423	24
Has FDA granted waiver/exception If yes, attach documentation from	n/exemption for pro m FDA.	oduct?	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc GTIN	r? e manufacturer for rep	ackaged product	Box/Carton/Bundle/ Inner Pack: Case:				4.5	423	24
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	oduct? GTIN Saleable	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc GTIN 0033	r? e manufacturer for rep I-14 1722655309	ackaged product	Box/Carton/Bundle/ Inner Pack: Case: Pallet:			8		423 ER USE ONL	
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	oduct? GTIN Saleable	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc GTIN 0033	e manufacturer for rep	ackaged product	Box/Carton/Bundle/ Inner Pack: Case: Pallet:	3.3		8			
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc GTIN 0033	r? e manufacturer for rep I-14 1722655309	ackaged product	Box/Carton/Bundle/ Inner Pack: Case: Pallet: C Regular Cost	3.3 OST INFORMATION	11.75	8 Vendor #:	WHOLESALI		
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc GTIN 0033	r? e manufacturer for rep I-14 1722655309	ackaged product	Box/Carton/Bundle/ Inner Pack: Case: Pallet:	3.3 OST INFORMATION	11.75	8 Vendor #: Whsi. Code	WHOLESALI		
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc GTIN 0033	r? e manufacturer for rep I-14 1722655309	ackaged product	Box/Carton/Bundled Inner Pack: Case: Pallet: C Regular Cost Invoice Cost (WAC)	OST INFORMATION (\$)	11.75	8 Vendor #:	WHOLESALI		
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc GTIN 0033	r? e manufacturer for rep I-14 1722655309	ackaged product	Box/Carton/Bundle/ Inner Pack: Case: Pallet: C Regular Cost	3.3 OST INFORMATION	11.75	8 Vendor #: Whsi. Code	WHOLESALI		
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No N AND HIBCC PRODUCT IN	direct Provid	from mf le sourc GTIN 0033	r? e manufacturer for rep I-14 1722655309	ackaged product	Box/Carton/Bundled Inner Pack: Case: Pallet: C Regular Cost Invoice Cost (WAC)	OST INFORMATION (\$)	11.75	8 Vendor #: Whsi. Code	WHOLESALI		
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1 24	Yes No NAND HIBCC PRODUCT IN HIBCC	IFORMATION	from mf le sourc GTIN 0033 2033	r? e manufacturer for rep I-14 1722655309 1722655303	ackaged product	Box/Carton/Bundley Inner Pack: Case: Pallet: C Regular Cost Invoice Cost (WAC) As of date:	(\$) 5/5/2022	11.75	8 Vendor #: Whsi. Code	WHOLESALI		
Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro m FDA. RFID tag(Y/N)	CTIN Saleable Quantity 1 24 24	Yes No NAND HIBCC PRODUCT IN HIBCC	IFORMATION	from mf le sourc GTIN 0033 2033	e manufacturer for rep I-14 1722655309 1722655303 d letter, PACKAGE INSE	Unit of Use GTIN-14 00331722655309	Box/Carton/Bundler Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WAC) As of date: PRODUCT PACKAGING	(\$) 5/5/2022	11.75	8 Vendor #: Whsi. Code	WHOLESALI		

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

Version 2024 For Designat	ted Drop Ship Only Products, Please Use Page 3					
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? 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? No d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? 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	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug? Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which:					
c. DOT Hazard Class	Hazardous Waste Identification					
d. Packing Group e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? No 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 No Limited Distribution Requirement Image: 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) Special Permit; DOT-SP	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Provider Name: DEA #: Site Enrollment Number assigned NPI #: by Supplier: NPI #:					
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments					
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 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 Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:					



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Version 2024	FOR DESIGNATED DROP SHIP PRODUCT ONLY -	if not a designated drop ship, do not complete.
Order Method for	r Designated Drop Ship Product	Standard Order Receipt and Processing
. ,	Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: 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:
	hone: es or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:		Overnight receipt available:
		Priority Overnight receipt available:
No restriction: Select YES if sold to retail phan Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician o Restricted from US territories? (explain in con Comments:	ffices only: ments)	PO Receipt Cut off time: Image: Constraint of the constr
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	mation Required to Process PO:	Return Instructions Return Instructions Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: URL/Link to returns policy:
Mis	scellaneous Notes:	
		ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?