

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

					In	troduction Type:	New Item	] [	x Final Version			Date:	6/12/	/2025
			PRODUCT INFORMAT	ION					SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceut	ticals, Inc.				Application:	ANDA	a. Temperature	e – Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN	DA/BLA; PMA/510(k)	): 212278			NDA	505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat														
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		e: Atazana	avir Capsules 200 mg						(write in)					
Selling Unit NDC:	31722-654-60		Unit of Use NDC:	31722-6			22654609		Notes					
UDI			CVX Code:		M	IVX Code:								
Description:	Atazanavir Capsules	s 200 mg							Is this product to be shippe				No	
								-	Is this product to be shippe	d to customers on o	dry ice?		No	
Active Ingredient(s):	A	Atazanavir sulfate						h Contact for	temperature excursion qu	actions:				
URL for Additional Product Inform	nation:	www.camberpharma.	com						Name:	estions:	Soma Raju			
Address:	800 Centennial Ave,				Add	ress 2:			Number:		732-529-042	3		
City:	Piscataway			Stat			: 08854		Group E-mail:		somaraju@h		n	
Key Contact:	Customer Service			Ema	ail: <u>custo</u>	omerservice@cam	berpharma.com		•					
Phone Number:	1-866-827-3647			Fax	<b>ix:</b> 732-	562-8788		c. Special regu	ulations for product in any	states?			No	
Product Therapeutic Classification	n: F	Protease inhibitor						_	Special returns requiremen	ts for this product?			No	
	L													-
	ADDITION	NAL PRODUCT INF	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Only					Protect product (unit of sa	ale) from light?			No	1
a legend device?	N	No	Is the Product	Unit of Use		Size:	60 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			5120.			Initial shelf life at launch (	if different):				Months
a product kit?	N	No			5	Strength:	200 mg							
if yes, list NDCs of			FDA Approval Status			•				ORDER INFOR	ATION			
component parts reverse numbered?		No				Dosage Form:	Hard gelatin capsule		Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present					l l	x Bottle		1 Bottle of 6		uniti	
latex-free?		Yes	Dairy, Lactose, Casein,	Whey, Alcohol, Anima	4		Capsule		Box/Carton			g. 1 Box of 10	0 Vials)	
preservative-free?		Yes	Prod		F	Product Shape:			Ampule		(	J		
correctional institution block?	N	No				Product Color:	Green opaque cap and		Glass		Minimum or	der quantity	?	Yes
opioid?		No					light green opaque body		Tube					
Cannabinoid?		No	Country of Origin	India	F	Product Imprint:	Imprinted with 'H' on cap in black color and 'A7' on body in black color		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for				-				Vial Liquid Multi				ch package t	type?
hospital scanning? If Unit Dose, indicate NDC here:	_		Is this product covered un Trade Agreements Act (T		_				Vial Powder Sgl Vial Powder Multi			Each Inner/Carton	(D 1-	
II Onit Dose, indicate NDC here.			Trade Agreements Act (1)	AA)? No					Other: Write In			Case	Pack	
			FOR GENERIC DRUG PRO						Other: Write III			Case		
			FOR GENERIC DRUG PRO											
					Authorize	d Generic *If A	uthorized Generic, other		PI		/ BILL UNIT			
I. Orange Book Rating:	AB													
II. Generic Equivalent to What Bra	AD			т —		sect	ion fields are not applicable	Roc coll unit t	o customor?	IARMACT ORDER	By billing u	ait to phorm		
II. Generie Equivalent to What Bra	nd2· R	levataz		I		sect	ion fields are not applicable	Rec. sell unit t	o customer?	IARMACT ORDER	Rx billing u		acy:	
	nd?: F	Reyataz				sect	ion fields are not applicable				Rx billing u	Each	acy:	
	nd?: F		CHAIN SECURITY ACT (E	DSCSA) INFORMATION		sect	ion fields are not applicable	Rec. sell unit t (Write-in, e.g. HCPCS J-Code	1 Vial)		Rx billing u		acy:	
	nd?: F		CHAIN SECURITY ACT (E	DSCSA) INFORMATION		sect	ion fields are not applicable	(Write-in, e.g.	1 Vial) e:	]		Each Gram Milliliter	acy:	
Does supplier meet DSCSA defini		DRUG SUPPLY	Yes	DSCSA) INFORMATION	4	sect 722498975	on rielos are not applicable	(Write-in, e.g.	1 Vial) e:	ARMACTORDER		Each Gram Milliliter	acy:	
Does supplier meet DSCSA definit Is product exempt from DSCSA?		DRUG SUPPLY		_	4		on rielos are not applicable	(Write-in, e.g.	1 Vial) e:	]		Each Gram Milliliter		
		DRUG SUPPLY	Yes	_	4		on tielos are not applicable	(Write-in, e.g.	1 Vial) e: ITEI	AND PACKING I		Each Gram Milliliter	-	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:		DRUG SUPPLY	Yes No	GLN:	0331	722498975		(Write-in, e.g. : HCPCS J-Code	1 Vial) e:	AND PACKING I	NFORMATION	Each Gram Milliliter	-	Saleable # Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	ition of manufacturer	DRUG SUPPLY	Yes No No	GLN: GCP: If yes, w	0331 vas original			(Write-in, e.g.	1 Vial) e: ITEI	I AND PACKING I Dimens Depth	NFORMATION	Each Gram Milliliter	Volume	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	ition of manufacturer	DRUG SUPPLY	Yes No No Yes	GLN: GCP: If yes, w direct fr	u 0331 vas original j rom mfr?	1722498975 product purchase	d	(Write-in, e.g. HCPCS J-Code	1 Vial) e: Vielght Lbs. 0.15	I AND PACKING I Dimens	NFORMATION ions (US msm Width	Each Gram Milliliter N tts.) Height	Volume (Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	tion of manufacturer	DRUG SUPPLY	Yes No No	GLN: GCP: If yes, w direct fr	u 0331 vas original j rom mfr?	722498975	d	(Write-in, e.g. HCPCS J-Code	1 Vial) e: Vielght Lbs. 0.15	I AND PACKING I Dimens Depth	NFORMATION ions (US msm Width	Each Gram Milliliter N tts.) Height	Volume (Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	tion of manufacturer	DRUG SUPPLY	Yes No No Yes	GLN: GCP: If yes, w direct fr	u 0331 vas original j rom mfr?	1722498975 product purchase	d	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack:	1 Viai) e: Weight Lbs. 0.15	AND PACKING I Dimens Depth 2.15	INFORMATION NFORMATION Width 2.15	Each Gram Milliliter M tts.) Height 3.9	Volume (Cube) 18.03	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	tion of manufacturer	DRUG SUPPLY	Yes No No Yes No	GLN: GCP: If yes, w direct fr Provide	u 0331 vas original j rom mfr?	1722498975 product purchase	d	(Write-in, e.g. HCPCS J-Code	1 Vial) e: Vielght Lbs. 0.15	I AND PACKING I Dimens Depth	NFORMATION ions (US msm Width	Each Gram Milliliter N tts.) Height	Volume (Cube)	Pieces
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from	tion of manufacturer	DRUG SUPPLY	Yes No No Yes No AND HIBCC PRODUCT IN	GLN: GCP: If yes, w direct fr Provide	0331 0331 rom mfr? source man	1722498975 product purchase hufacturer for rep:	dackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case:	1 Viai) e: Weight Lbs. 0.15	AND PACKING I Dimens Depth 2.15	INFORMATION NFORMATION Width 2.15	Each Gram Milliliter M tts.) Height 3.9	Volume (Cube) 18.03	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	tion of manufacturer	DRUG SUPPLY ?  pr? juct? GTIN Saleable	Yes No No Yes No AND HIBCC PRODUCT IN	GLN: GCP: If yes, w direct fr Provide	vas original   rom mfr? e source man	1722498975 product purchase hufacturer for rep:	d	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case:	1 Viai) e: Weight Lbs. 0.15 andle/ 4.1	AND PACKING I Dimens Depth 2.15	NFORMATION ions (US msm Width 2.15 9.25	Each Gram Milliliter tts.) Height 3.9 5	Volume (Cube) 18.03 635.94	Pieces           1           24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	tion of manufacturer tion of manufacturer texclusive distributo n/exemption for prod m FDA.	DRUG SUPPLY ?  pr? duct?  GTIN Saleable Quantity 1	Yes No No Yes No AND HIBCC PRODUCT IN	GLN: GCP: If yes, w direct fr Provide	0331 0331 room mfr? e source man GTIN-14	1722498975 product purchase nufacturer for repo	dackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case:	1 Viai) e: Weight Lbs. 0.15	AND PACKING I Dimens Depth 2.15	NFORMATION ions (US msm Width 2.15 9.25	Each Gram Milliliter tts.) Height 3.9 5	Volume (Cube) 18.03	Pieces           1           24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Bov/Carton/Bundie/Inner Pack Case	tion of manufacturer exclusive distributor n/exemption for prod m FDA. RFID tag(Y/N) S C	DRUG SUPPLY ?  pr? juct? GTIN Saleable	Yes No No Yes No AND HIBCC PRODUCT IN	GLN: GCP: If yes, w direct fr Provide	0331 0331 rom mfr? source man	1722498975 product purchase nufacturer for repo	dackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet:	1 Viai) e: Weight Lbs. 0.15 andle/ 4.1	AND PACKING I Dimens Depth 2.15	NFORMATION NFORMATION Width 2.15 9.25	Each Gram Milliliter tts.) Height 3.9 5	Volume (Cube) 18.03 635.94	Pieces           1           24
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Bov/Carton/Bundie/Inner Pack Case	tion of manufacturer tion of manufacturer texclusive distributo n/exemption for prod m FDA.	DRUG SUPPLY ?  pr? duct?  GTIN Saleable Quantity 1	Yes No No Yes No AND HIBCC PRODUCT IN	GLN: GCP: If yes, w direct fr Provide	0331 0331 room mfr? e source man GTIN-14	1722498975 product purchase nufacturer for repo	dackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet:	1 Viai) e: Weight Lbs. 0.15 indie/ 4.1 COST INFORMATION	AND PACKING I Dimens Depth 2.15 13.75	NFORMATION ions (US msm Width 2.15 9.25 Vendor #: Whsl. Code	Each Gram Milliliter Its.) Height 3.9 5 5 WHOLESALL	Volume (Cube) 18.03 635.94	Pieces           1           24
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Bov/Carton/Bundle/Inner Pack Case	tion of manufacturer tion of m	DRUG SUPPLY ?  pr? juct?  GTIN Saleable Quantity 1 24 24	Yes No No Yes No AND HIBCC PRODUCT IN HIBCC	GLN: GCP: If yes, w direct fr Provide	0331 orom mfr? e source man GTIN-14 003317226 203317226	1722498975 product purchase hufacturer for rep: 354609 354603 r, PACKAGE INSE	dackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet: Regular Cost Invoice Cost (N As of date: PRODUCT PACKAG	1 Viai) e: Weight Lbs. 0.15 andle/ 4.1 COST INFORMATION NAC) (\$) 5/5/2022	AND PACKING I Dimens Depth 2.15 13.75	NFORMATION ions (US msm Width 2.15 9.25 Vendor #: Whsl. Code	Each Gram Milliliter Its.) Height 3.9 5 5 WHOLESALL	Volume (Cube) 18.03 635.94	Pieces           1           24

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

Version 2024 For Designa	ted Drop Ship Only Products, Please Use Page 3				
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No 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?     A     Ooes 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, No identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? 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?					
(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     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 Special Pervision (listed in Column 7 of 49 CFR 172.101);	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 #:				
SP#	Registry: No				
	Registry Program Contact Name: Phone:				
ADD'L STORAGE INFORMATION	Comments				
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS       Contact tel. # if product received damaged:     1-866-827-3647       Is product returnable for credit:     Yes       URL/Link to returns policy:				
	contact - customerservice@camberpharma.com				
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	Special regulations or returns requirements for this product in certain states? No				
Restricted from US territories? (explain in comments)     No       Comments:	If so, which states? Other requirements? Comments?				
	OUS NOTES and/or Image of Product Barcode:				
MISCELLANE					



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

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?