

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

Version 2021						Introduction Typ	pe: New	v Item		x Final Version			Date:	5/4/2	2022
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						NDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	NDA/BLA (drug); PN	/IA/510(k)(med device	ce):	212	2278				1	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica			·						Ť l	· -					
DUNS:	11-856-3719								*	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Atazar	navir Capsules 150 mg						I	(write in)					
Selling Unit NDC:	31722-653-60		Unit of Use NDC		31722-653-60		331722653602			Notes					
UDI			CVX Code:			MVX Code:			1						
Description:	Atazanavir Capsu	les 150 mg							Ţ	Is this product to be shippe	d to customers on	ice?		No	
										Is this product to be shippe				No	
Active Ingredient(s):		Atazanavir							I						
									b. Contact for	r temperature excursion qu	estions:				
URL for Additional Product Inform									1	Name:		Soma Raju			
Address:		Ave (and) 800 Center	nnial Ave, Suite 1		State:	Address 2:	71		-	Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:		Zip: 08854 e@camberpharm		-	Group E-mail:		<u>somaraju(</u>	heterousa	a.com	
Phone Number:	1-866-827-3647	,			Fax:	732-562-8788	ешсаниегрнани	ia.com	c Special rec	julations for product in any	statos?			No	1
Product Therapeutic Classification		Protease Inhibitor			l ux.	732 302 3700			C. Opeciai reg	Special returns requirement				No	1
Troduct Therapeutic Glassification	JII.	1 Totcasc Illinoitor								Special returns requiremen	is for this product:			140	1
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT DE	ESCRIPTION INFOR	RMATION	d Store prod	uct (unit of sale) upright?				No	1
The weeduct is 2				Direct-Ship O	Inly	T NODGO I DE			1 a. o.o.o prou		ala) frama l'atro				1
The product is? a legend device?		No	Is the Product Is the Product	Unit of Use	n n y		60 ct		e. Shelf life:	Protect product (unit of sa	iie) from light?			No 24	Months
if yes, enter class #		INU	Orphan Drug Status	Offic of OSE		Size:	ou ct		e. Shelf life:	Initial shelf life at launch (	if different\-			24	Months Months
a product kit?		No	Orphan Drug Status				150 mg			initial Shell life at launch (	ii dillerent).				Wionins
if yes, list NDCs of		140	FDA Approval Status			Strength:	100 mg				ORDER INFOR	MATION			
component parts						B F	Hard gelatin c	capsule							
reverse numbered?		No				Dosage Form:		•		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					•		x Bottle		1 Bottle of 3	Capsules		
latex-free?		Yes				Product Shape	Capsule			Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				1 Todact Onapo	••			Ampule					
correctional institution block?		No				Product Color:	Green opaque			Glass		Minimum o	der quantity	/?	Yes
opioid?		No					green opaque			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprir	nt: 'H' on cap and	d 'A6' on		Vial Liquid Sgl					_
If Unit Dose, is item bar coded to u	unit dose for		to the construct account of	on don't be			body			Vial Liquid Multi				ich package t	rype?
hospital scanning?			Is this product covered Trade Agreements Act (		No					Vial Powder Sql Vial Power Multi		24	Each Inner/Carton	/Deals	
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)!	INO					Other: Write In			Case	/Pack	
			FOR GENERIC DRUG PF	CODUCTS					1	Other. Write in			Case		
			TOR GENERIC DROG FI	1000013											
					Aut	horized Generic *	*If Authorized Generi	ric other		PH	IARMACY ORDER	R / BILL UNIT			
L Oranga Baak Batings	AB			_			section fields are not		Pac sall unit	to customer?					
I. Orange Book Rating: II. Generic Equivalent to What Bra		Reyataz						•••	Nec. sen unit	to customer:	1	KX billing u	nit to pharm Each	acy:	
ii. Generic Equivalent to what Bra	anu r.	rreyataz							(Write-in, e.g.	1 Vial)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	MATION				(vviito iii, o.g.	· · · · · · · ·			Milliliter		
				,											
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes		GLN:	0331722000000				ITEN	AND PACKING	INFORMATIO	1		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:				1		Dimens	ions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was ori	ginal product purch	nased		Item/Each:	0.11	1.9	1.9	3.5	12.64	1
Is product sold by manufacturer's			Yes		direct from mf						1.5	1.5	3.3	12.04	'
Has FDA granted waiver/exception		oduct?	No		Provide sourc	e manufacturer for I	repackaged produc	ct	Box/Carton/B	Sundle/					
If yes, attach documentation fro	om FDA.								Inner Pack:						
		0.71	N AND LUDGO BRODUCT	NEODMATION					Case:	3.2	12	8	4.65	446.40	24
		GII	N AND HIBCC PRODUCT I	NFORMATION					Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTIN	1.1.1	Unit of Use (	CTIN 14	Pallet:						
X Item/Each	5	aleable Quantity	ITIDOC			N-14 N-1722653602	0033172265								
Box/Carton/Bundle/Inner Pack					3033	2200002	0000172200	00002		COST INFORMATION			WHOLESAL	ER USE ONL	Y:
and an		24			2033	1722653606									
X Case									Regular Cost			Vendor #:			
X Case Pallet															
									Invoice Cost	(WAC) (\$)	\$178.20	Whsl. Code	#:		
									Invoice Cost	(WAC) (\$)	\$178.20	Whsl. Code Fineline Co			
									As of date:	(WAC) (\$)	\$178.20				
										(WAC) (\$)	\$178.20				
									As of date:		\$178.20				
			Attach copy of SAFETY D	ATA SHEET (SD	S) or non hazar		NSERT, LABEL AND		As of date:		\$178.20				



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic?  No	SDS Hazard Classification						
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?  No  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?	Tacto statutulos						
(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?  RQ Threshold:  Is this a marine pollutant?  No  Is this product shipped utilizing an authorized DOT exception or Special Permit?  (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#:  NCPDP#:  NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product  Controlled Substance?  Controlled Substance Code  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:  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?						
Comments:	1 30, miles states. Other requirements: Continuities:						
MISCELLANE	OUS 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?