

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

						Introduction ⁻	Туре:	New Item		x Final Version			Date:	5/4/2	2022
			PRODUCT INFORMAT	ION						SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceutic	cals Inc				Applica	tion:	ANDA	a Temperatur	re - Indicate the USP tempe	rature range for t	his product			
Application Number for NDA/AN			ce).	2	12278	7.400.00		741571	u. remperatur	Temperature Range	Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical										·					
DUNS:	11-856-3719								-	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established Name	: Atazan	avir Capsules 200 mg							(write in)					
Selling Unit NDC:	31722-654-60		Unit of Use NDC:		31722-654-60	UPC:	331722654	4609		Notes					
UDI			CVX Code:			MVX Code:									
Description:	Atazanavir Capsules 2	200 mg								Is this product to be shipped	to customers on ic	ce?		No	
										Is this product to be shipped	to customers on d	iry ice?		No	
Active Ingredient(s):	Ata	azanavir													
									b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform					_				_	Name: Number:		Soma Raju			
Address:		Centennial Ave (and) 800 Centennial Ave, Suite 1			State:	Address 2: NJ Zip: 08854			-	732-529-0423					
City: Key Contact:	Piscataway Customer Service				Email:	-	ustomerservice@camberpharma.com		-	Group E-mail:			somaraju@heterousa.com		
Phone Number:	1-866-827-3647				Fax:	<u> </u>		nce@camberpharma.com		c. Special regulations for product in any states?				No	
Product Therapeutic Classificatio		otease Inhibitor			- · uni	702 002 0700			o. opeoidi regi	Special returns requirement				No	
Troduct Therapeutic Glassificatio		otease minibitor								opecial returns requirement	s for this product:			140	
	ADDITIONA	AL PRODUCT INF	ORMATION			PRODUCT	DESCRIPTION	ON INFORMATION	d. Store produ	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only				1	Protect product (unit of sa	ala) from light?			No	
a legend device?	No		Is the Product	Unit of Use	Offiny		60 (~†	e. Shelf life:	Frotect product (unit of Sa	ale) Irom light?			24	Months
if yes, enter class #	140	,	Orphan Drug Status	01.11 01 000		Size:	00 (St.	C. Onen me.	Initial shelf life at launch (if different):			24	Months
a product kit?	No)				01	200	mg		,					
if yes, list NDCs of			FDA Approval Status			Strength:		· ·			ORDER INFORM	ATION			
component parts						Dosage For	m. Har	d gelatin capsule							
reverse numbered?	No					Doougo . c				Unit of Sale		What is the		unit?	
co-licensed?	No		Allergens Present							x Bottle		1 Bottle of 60			
latex-free?	Ye					Product Shape: Capsule				Box/Carton			(Write-in, e.g. 1 Box of 10 Vials)		
preservative-free? correctional institution block?	Yes						Cro	en opaque cap and		Ampule Glass		Minimum or	dor augntiti	w2	Yes
opioid?	No No					Product Col		t green opaque body		Tube		wimimum or	der quantity	/:	res
Cannabinoid?	No		Country of Origin	India			442	on cap and 'A7' on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u			,g			Product Imp	print:			Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?			Is this product covered ur	nder the						Vial Powder Sql			Each		**
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No					Vial Power Multi			Inner/Cartor	ı/Pack	
]	Other: Write In			Case		
		I	FOR GENERIC DRUG PRO	DUCTS											
					Autl	norized Generic		zed Generic, other		PH	ARMACY ORDER	BILL UNIT			
I. Orange Book Rating:	AB				Autl	norized Generic		zed Generic, other lds are not applicable	Rec. sell unit		ARMACY ORDER	/ BILL UNIT Rx billing u		acy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		eyataz			Auti	norized Generic				to customer?	ARMACY ORDER		Each	acy:	
		•	/ CHAIN SECURITY ACT /	DSCSA) INFO		norized Generic			Rec. sell unit	to customer?	ARMACY ORDER		Each Gram	асу:	
		•	' CHAIN SECURITY ACT (E	DSCSA) INFO		norized Generic				to customer?	ARMACY ORDER		Each	nacy:	
	and?: Re	DRUG SUPPLY	CHAIN SECURITY ACT (E	DSCSA) INFO		0331722000000	section fiel			to customer?	ARMACY ORDER	Rx billing u	Each Gram Milliliter	nacy:	
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defini 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	DSCSA) INFO	GLN: GCP: If yes, was ori purchased dir	0331722000000 ginal product ect from mfr?	section field	lds are not applicable	(Write-in, e.g.	to customer? 1 Vial) TEM Weight Lbs. 0.15	AND PACKING IN	Rx billing under the state of t	Each Gram Milliliter	Volume	
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X	ition of manufacturer? s exclusive distributor on for production	PRUG SUPPLY Property GTIN able Quantity	Yes No No Yes No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was ori purchased dir Provide source GTIM 0033	0331722000000 ginal product ect from mfr? e manufacturer f	section fiel	ged product	(Write-in, e.g. Item/Each: Box/Carton/Bilnner Pack: Case: Pallet:	to customer? 1 Vial) Weight Lbs. 0.15 undle/ 4.1 COST INFORMATION	AND PACKING IN Dimensic Depth 2.1 13	Rx billing under the second se	Each Gram Milliliter Auts.) Height 4 5.25	Volume (Cube) 17.64 614.25	Pieces 1 24
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL F	HAZARD 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? (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? 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: Phone: DEA #: NCPDP#: NCPDP#: NPI #:						
Special Permit; DOT-SP 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)? 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	Contact tel. # if product received damaged: Is product returnable for credit: RETURN INSTRUCTIONS 1-866-827-3647 Yes						
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: 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:							
MISCELLAN	NEOUS NOTES and/or Image of Product Barcode:						



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

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	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, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process 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?