

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

Version 2021						Introduction	Туре:	New Item		x Final Ve	sion			Date:	6/23/	2024
			PRODUCT INFORMA	TION						SPEC	IAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.					Applica	Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANI	blication Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 202083 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)															
Medical Device Class, if applicab	Medical Device Class, if applicable:															
DUNS:	11-856-3719									Other Temperatur	e Range R	equirement				
Proprietary Name (If Applicable) a		Daruna	vir Tablets 600 mg							(write in)						
Selling Unit NDC:	31722-568-60		Unit of Use NDC:		31722-568-60		33172256	68609		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Darunavir Tablets 600 m	g								Is this product to b					No	
Active Instruction (a) Is this product to be shipped to customers on dry ice? No																
Active Ingredient(s): Darunavir b. Contact for temperature excursion questions:																
URL for Additional Product Inform	ation:	camberpharma.	com							Name:	i sion que	510115.	Soma Raju			
Address:					Address 2:				Number:				3			
City:	Piscataway State: N				NJ						somaraju@heterousa.com					
Key Contact:	Customer Service				Email:	customerservice	e@camberph	harma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788				ulations for produ	-				No	
Product Therapeutic Classification	n: Huma	an immunodefic	ciency virus (HIV-1) proteas	e inhibitor						Special returns re	quirements	for this product?			No	
	ADDITIONAL					PRODUCT	DESCRIPT	ION INFORMATION	d Store prod	uct (unit of sale) u	vright?				No	
	ADDITIONAL	RODUCTINF		Direct Ohlin C	Delta	PRODUCT	DESCRIPT	TON INFORMATION	u. Store produ		-					
The product is?	N		Is the Product	Direct-Ship C Unit of Use	лпу		00	) at	a Chalf IV	Protect product (	unit of sale	e) from light?			No	Mantha
a legend device? if yes, enter class #	No		Is the Product Orphan Drug Status	onit of ose		Size:	60	CL .	e. Shelf life:	Initial shelf life at	launch /if	different).			24	Months Months
a product kit?	No		Orphan Drug Status				60	00 mg		initial shell life at	iauricri (ii	umerenty.				WOILIIS
if yes, list NDCs of			FDA Approval Status			Strength:						ORDER INFORM	IATION			
component parts						Dosage For	·m· Fil	m-coated tablet								
reverse numbered?	No					Dosugeron				Unit of Sale				NDC selling	unit?	
co-licensed?	No		Allergens Present							x Bottle			1 Bottle of 6			
latex-free?	Yes					Product Sha	ape: Ov	val, biconvex		Box/Car	on		(Write-in, e.	g. 1 Box of 10	) Vials)	
preservative-free? correctional institution block?	Yes						Or	ange		Ampule Glass			Minimum or	der quantity	<b>,</b>	Yes
opioid?	No					Product Col	lor:	ange		Tube			winninum or	uer quantity	f	Tes
Cannabinoid?	No		Country of Origin	India		Developed		bossed with 'J' on one side		Vial Liqu	id Sgl					
If Unit Dose, is item bar coded to u	init dose for					Product Imp	print: and	d '7' on the other side		Vial Liqu				many of whi	ch package t	type?
hospital scanning?			Is this product covered u							Vial Pow				Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No					Vial Pow				Inner/Carton	/Pack	
										Other: W	rite In		1	Case		
	FOR GENERIC DRUG PRODUCTS															
					Au	thorized Generic	*If Author	ized Generic, other		PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB							elds are not applicable	Rec. sell unit	to customer?			Rx billing u	nit to pharma	ncv.	
II. Generic Equivalent to What Brand?: Prezista												Each				
						(Write-in, e.g.	1 Vial)				Gram					
		DRUG SUPPL	Y CHAIN SECURITY ACT (	(DSCSA) INFOR	RMATION									Milliliter		
Deep overalies most DSCSA definit	tion of monufactures?		Voo		CI NI	0331722498975					ITEM	AND PACKING I	FORMATION	a		
Does supplier meet DSCSA definit Is product exempt from DSCSA?	uon or manufacturer?		Yes	-	GLN:	0331722498975					- TEM	AND FACKING I				
			. 10		GCP:							Dimonsi	ons (US msm	te )	Volume	Saleable #
If yes, select exemption: Other exemption - Write in:					GUP:					Weig	nt Lbs.	Dimensi	ons (US msm Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If ves, was or	iginal product pur	rchased		Item/Each:							
Is product sold by manufacturer's	exclusive distributor?		Yes	-	direct from m					0	26	2.19	2.19	3.88	18.61	1
Has FDA granted waiver/exception		?	No		Provide source	ce manufacturer f	or repackag	ged product	Box/Carton/B	undle/						
If yes, attach documentation from	n FDA.								Inner Pack:							
		GTIN	N AND HIBCC PRODUCT I						Case:	6	85	13.5	9.5	5	641.25	24
		GII	ANDTIBECTRODUCT	NICKMATION					Pallet:							
Saleable Unit of Measure	Saleable	e Quantity	HIBCC		GTI	N-14	ι	Unit of Use GTIN-14	i anct.							
X Item/Each		1				31722568609		00331722568609	·							
Box/Cartor/Bundle/Inner Pack								COST INFORMATION				WHOLESALER USE ONLY:				
X Case	:	24			203	31722568603	_									
Pallet					_		_		Regular Cost		-	Acc	Vendor #:	4.		
	-						-		Invoice Cost (	VVAC) (\$)	ŀ	\$99.00	Whsl. Code Fineline Co			
							-		As of date:	12/8/202	3					
													1			
			Attach copy of SAFETY DA	ATA SHEET (SE	S) or non haza				RODUCT PACKA	GING and BARCO	DE.					
*Please provide any additional info	ormation on page 2.					See new p. 3 fo	r Designate	ed Drop Ship Only.		Signature:						

## HDA🔾

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

Version 2021 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? 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? 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 No No No No No No No N	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:						
a. On/definition for holder     b. Proper Shipping Name     c. DOT Hazard Class     d. Packing Group     e. Inhalation Hazard?     Is this product regulated for shipment by IATA?     No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:						
(if yes, answer a-e below and provide SDS)       a. UN/Identification Number       b. Proper Shipping Name       c. DOT Hazard Class       d. Packing Group       e. Inhalation Hazard?	REMS or REGISTRY RESTRICTIONS         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 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) Special Permit; DOT-SP	REMS:     No       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:						
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	No       Registry Program Contact Name:       Comments						
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. 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: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com						
No     No       Restricted to retail pharmacy only:     No       Restricted to hospital, clinics, and physician offices only:     No       Restricted from US territories? (explain in comments)     No       Comments:     No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
MISCELLANE	OUS 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         c. Fax         d. Phone only         e. Supplier Web Site only         Minimum Order Quantity:         Supplier's Customer Service Number:         Contracted 3PL company / contact #:         Name:         Phone:	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:
Expedited Freight Charges 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:       Image: Comparison of the co
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:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?