

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

						Introduction Type:	New Item	X	Final Version			Date:	9/26/	
			PRODUCT INFORMAT	TION					SPECIAL HANDI	LING AND STORA	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals. Inc.				Application:	ANDA	a. Temperature – Indica	ate the USP tempera	ature range for th	is product.			
Application Number for NDA/ANI	DA/BLA: PMA/510	(k): 216168				NDA 505(b) Type:	NOT APPLICABLE			Controlled Room –		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab						. , , , ,		TI '	, L					
DUNS:	11-856-3719							Other Te	emperature Range Re	equirement	Excursions p	ermitted to 1	5°C to 30°C (59°F to
Proprietary Name (If Applicable) as	nd Established Na	me: Darunav	ir Tablets 800 mg						ite in)		86°F)			
	31722-089-30		Unit of Use NDC:		31722-089-30	UPC: 331	722089302	Notes	•					
UDI			CVX Code:			MVX Code:		1						
Description:	Darunavir Tablets	800 ma						ls this no	oduct to be shipped to	to customers on ic	e?		No	
Description.	Daranavii Tabicis	ooo mg							oduct to be shipped to				No	
Active Ingredient(s):		Darunavir amorphous									,			
5 (,,		,						b. Contact for temperat	ture excursion ques	stions:				
URL for Additional Product Inform	ation:	www.camberpharma.c	com					Name:			Soma Raju			
Address:	800 Centennial A	re, Suite 1				Address 2:		Number	:		732-529-042			
City:	Piscataway				State:	NJ Zip	08854	Group E	-mail:		somaraju@h	eterousa.con	<u>1</u>	
Key Contact:	Customer Service				Email:	customerservice@cam	berpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations f	for product in any st	tates?			No	
Product Therapeutic Classification	1:	Human immunodefici	ency virus (HIV-1) protease	e inhibitor				Special r	returns requirements	for this product?			No	
								_						
	ADDITI	ONAL PRODUCT INFO	DRMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit of	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly			Protect	product (unit of sale	e) from light?			No	
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			Size.		Initial sh	nelf life at launch (if	different):				Months
a product kit?		No				Strength:	800 mg							
if yes, list NDCs of			FDA Approval Status			ou ongui.				ORDER INFORM	ATION			
component parts						Dosage Form:	Film-coated tablet							
reverse numbered?		No						Unit of S			What is the		unit?	
co-licensed?		No	Allergens Present					x	Bottle		1 Bottle of 3			
latex-free?		Yes				Product Shape:	Oval, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?		Yes					Yellow		Ampule		Minimum an		•	Vaa
correctional institution block? opioid?		No No				Product Color:	reliow		Glass		Minimum or	uer quantity	ſ	Yes
Cannabinoid?		No	Country of Origin	India			Debossed with 'V' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for	INU	Country of Origin	IIIuia		Product Imprint:	and '7' on the other side		Vial Liquid Sgi		If Yes, how	nany of whi	ch nackado i	hyno?
hospital scanning?	THE GOSE TO		Is this product covered ur	nder the					Vial Powder Sgl			Each	cii package	ype:
If Unit Dose, indicate NDC here:			Trade Agreements Act (T.									Inner/Carton	/Deals	
					INO I				Vial Powder Multi					
			Trade rigidements riot (1.	AA)?	No				Vial Powder Multi Other: Write In			Case	Pack	
					No								Pack	
			FOR GENERIC DRUG PRO		No								Pack	
						thorized Generic *If A	uthorized Generic, other		Other: Write In	RMACY ORDER A			Pack	
I. Orange Book Rating:	AB						uthorized Generic, other ion fields are not applicable	Rec. sell unit to custon	Other: Write In		BILL UNIT	Case		
I. Orange Book Rating: II. Generic Equivalent to What Brar	AB nd?:	Prezista						Rec. sell unit to custon	Other: Write In			Case		
		Prezista	FOR GENERIC DRUG PRO	ODUCTS	Au			(Write-in, e.g. 1 Vial)	Other: Write In		BILL UNIT	Case nit to pharma Each Gram		
		Prezista		ODUCTS	Au				Other: Write In		BILL UNIT	Case nit to pharma Each		
II. Generic Equivalent to What Bran	nd?:	Prezista DRUG SUPPLY	FOR GENERIC DRUG PRO	ODUCTS	Au	sect		(Write-in, e.g. 1 Vial)	Other: Write In PHA		/ BILL UNIT Rx billing u	Case iit to pharma Each Gram Milliliter		
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II. Generic Equivalent to What Branch Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?:	Prezista DRUG SUPPLY	FOR GENERIC DRUG PRO CHAIN SECURITY ACT (I	ODUCTS	Au RMATION GLN: GCP:	sect	ion fields are not applicable	(Write-in, e.g. 1 Vial) HCPCS J-Code:	Other: Write In PHA	AND PACKING IN	BILL UNIT Rx billing ui	Case iit to pharma Each Gram Milliliter	асу:	Saleable # Pieces
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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION		
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	No	SC	S Hazard Classification	
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 No No	x Organic Inorganic Steroid/Androgen	Corrosive Oxidizer 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 No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No	
c. DOT Hazard Class d. Packing Group		Haza EPA Hazardous Waste Code:	rdous Waste Identification	Waste Characteristics
e. Inhalation Hazard? Is this product regulated for shipment by IATA?	No	EFA Hazardous Waste Code.		Waste Characteristics
(if yes, answer a-e below and provide SDS)		REMS o	r 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:	No	
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No	
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)		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#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments		
SP#		Registry: Registry Program Contact Name:	No	Phone:
ADD'L STORAGE INFORMATION		Comments		Thoric.
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	No	RI	ETURN INSTRUCTIONS	
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 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 - customerse	rvice@camberpharma.com	
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only:	No No	Special regulations or returns requirements for this product in certain states?	No	
Restricted from US territories? (explain in comments) Comments:	No	If so, which states? Other requirements? Comments?		
MI	SCELLANEC	US 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.

Purchase order ally receipt cut off time by supplier a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No. Expedited freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:
d. Phone only e. Suppler Web Site only Site Address: Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Days of week overnight for ceipt: Days of week overnight for ships for ceipt files: Days of week overnight for ships for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days			
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL. company / contact #: Name: Phone: Expedited Freight Carlanges or Other Designated Drop Ship Fees: Expedited Freight Carlanges or Other Designated Drop Ship Fees: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees bi			Shipping lead time of PO: Hours Days
Minimum Order Quantity: Supplier's Coutement Service Number: Contracted 3PL company / contact #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight (Fees pilled) with each order: Drop Ship service fee billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: 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 to robspital, clinics, and physician offices only: Comments: Other Data Information Required to Process PO: Patient Procedure Data: Physician Clinic Pance # Physician Clinic Specialty: Mitcellaneous Notes: Mitcellaneous Notes: Ships rescond day receipt: Overnight receipt available: Po Receipt Cut off time: Drop Repetited to robspital, clinics, and physician offices only: Po Receipt Cut off time: Po Receipt Cut off time: Saturday Overnight receipt available: Po Receipt Cut off time: Po Receipt Cut off time: Saturday Overnight receipt available: Po Receipt Cut off time: Order receipt method: Po Receipt Cut off time: Order	,		China annua dan faranat dan mariat
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