

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction Type:	Post Launch Change		Final Version			Date:	4/17	/2017
			PRODUCT INFORMATION	V				SPECIAL HANDL	ING AND STO	RAGE REQI	JIREMENTS*	•	
Company Name:	Camber Pharmaceuti	cale			Applicatio	n: ANDA	a. Temperature – Indio	ata the UCD tamper	oturo rongo f	or this produ	ıot		
Application Number for ND			1	79124	Applicatio	n. ANDA		iture Range	ature range i			en 20 and 25	C (68° – 77° F
		miros ro(k)(med device)	·-	10121			-	=		- CONTROLLOG TO		011 20 4114 20	0 (00
DUNS:	82-667-4775			10/0407				emperature Range Re	quirement				1
Proprietary Name (If Applical		Name: Lamivudii	ne and Zidovudine 150MG/300M		UDO 0047	2050204	(w	rite in)]
Selling Unit NDC:	31722-506-60 NA		Individual Unit NDC:	31722-506-60		22506601				0		N1.	
UDI			CVX Code:		MVX Code: NA			oduct to be shipped to				No	_
Description:	White to off-white cap	sule shpaed tablet embos	ssed with 'I' on the upper punch a	and '115' on the lower punc	ch .		Is this pr	oduct to be shipped to	o customers o	n dry ice?		No	_
		1					_						
Active Ingredient(s):		Lamivudine and Zidovud	ine				b. Contact for tempera	ature excursion que	stions:				
UDL for Additional Box book by		www.camberpharma.com					Name:			Soma Raju 732-529-042	22		
URL for Additional Product In Address:	1031 Centennial Ave		"		Address 2:		Number				eterousa.cor		
City:		iue				00054	Group E	:-maii:		somaraju@n	eterousa.cor	11	
Key Contact:	Piscataway State: NJ Zip: 08854 Customer Service Email: customerservice@camberpharma.com					c Special regulations	for product in any c	tatos?			No		
Phone Number:	Customer Service Email: customerservice@camberpharma.com				orphame.com	c. Special regulations for product in any states? Special returns requirements for this product? No					-		
Product Therapeutic Classifi					102 002 0100		opodian	otamo roquiromonto i	or and produc			110	_
Product Therapeutic Classiii	ication.						d Ctana mandriat (rimit	af aala)inb40				NI=	
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	AL PRODUCT IN ORW	ATION		r i	CODUCT DESCRIPTION	IN ORMATION		product (unit or sale	e) irom ngmr		i		-
Is the Product							e. Shelf life:					24	Months
a legend device?		No		Size:	60		Initial sh	nelf life at launch (if o	different):				Months
reverse numbered?		No No							ORDER INFOR	MATION			
co-licensed?		Direct-Ship Only		Strength:	150 mg			,	JRDER INFOR	RIVIATION			
Is the Product Is the Product		Unit of Use					Unit of S	Pala		What is the	NDC selling	unit?	
is the Floduct		Offic of OSC		Dosage Form:	Oral solid tablet		Onit or s	Bottle		1 box of 12 l		unit.	
							' x	Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?					1	Ampule		(g	,	
If Unit Dose NDC, indicate NI	DC here:			Product Shape:	capsule shaped			Glass		Minimum or	der quantity	?	Yes
				Product Color:	hite to effhtie			Tube					
Country of Origin		India		Product Color:	white to off-white	•		Vial Liquid Sgl					
Is this product covered under	r the Trade Agreements	Act (TAA)2		Product Imprint	: 1'/'115'			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
is this product covered under	i the fraue Agreements	No No		1 Toddot imprint	. 1/110			Vial Powder Sql			Each		
							11	Vial Power Multi		12	Inner/Carton	/Pack	
				10.00				Other: Write In	_		Case		
			FOR GENERIC DRUG PRODU	ICTS				Other: Write In			Case		
			FOR GENERIC DRUG PRODU						RMACY ORDE	D / DILL LINE	,		
	_		FOR GENERIC DRUG PRODU			athorized Generic, other section		PHAR	RMACY ORDE		Т		
I. Orange Book Rating:	AB	T	FOR GENERIC DRUG PRODU			thorized Generic, other section are not applicable	Rec. sell unit to custo	PHAR	RMACY ORDE		T	асу:	
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				Authori			Rec. sell unit to custo (Write-in, e.g. 1 Vial)	PHAR	RMACY ORDE		T nit to pharma Each Gram	асу:	
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):		·
a. Cytotoxic?	SDS Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GIAGGIRIGATORI	
Is the product a CA Prop 65 carcinogen?	Organic Corrosive	
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer	
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard	
a Contact Haranda	A arread Class Identify NEDA Ctarage Levels	
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:	
d. Does this product require special clean-up instructions? No		
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?	
e. Does the product contain DEHP?	If yes, indicate which:	
Is this product regulated for shipment by DOT or IATA? No		
(if yes, answer a-e below and provide SDS)		
a. UN/Identification Number		
b. Proper Shipping Name	Hazardous Waste Identification	
c. DOT Hazard Class	EPA Hazardous Waste Code: NA	
d. Packing Group		
e. Inhalation Hazard?		
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS	
Passenger	Is there a REMS on this product?	
Cargo	If Yes, is it managed with a pharmacy registry?	
Passenger & Cargo	Website URL:	
	Website ORL.	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant? No		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		
No (if yes, identify method below)	REMS:	
Limited Quantity	REMS Program Manager Name: Phone:	
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No	
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No No	
Special Permit; DOT-SP	Provider Name:	
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No	
SP#	by Supplier: PCPDP #: No)
<u></u>	NPI #: No)
ADD'L STORAGE INFORMATION		
Is the Product	Comments	
Controlled Substance? No		
Controlled by State(s)?	Registry: No	
ARCOS Reportable? No	Registry Program Contact Name: Phone:	
Schedule No. (inc. N for non-narcotic)	Comments	
Controlled Substance Code		
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS	
If yes, indicate which:		
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430	
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:	
N c c		
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	URL/Link to returns policy: contact - customerservice@camberpharma.com	
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states? No	
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments) No		
Comments:		
MISCELLAI	ANEOUS NOTES and/or Image of Product Barcode:	



Standard Pharmaceutical Product Information (Page 3)

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 Yes No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern				
c. Fax d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days				
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No				
Minimum Order Quantity: case pack	Ships for second day receipt: No				
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt: Yes				
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: No No	Overnight receipt available: Yes				
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern				
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:				
Comments:	x Tuesday x Wednesday Thursday x Friday				
	Priority Overnight receipt available: Yes				
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No				
Restricted to retail pharmacy only: Yes	PO Receipt Cut off time:				
Restricted to hospital, clinics, and physician offices only: No	Order receipt method: No Phone #:				
Restricted from US territories? (explain in comments) No	Fax: Yes Fax #: 732-562-8788				
Comments:	EDI: Yes				
	Overnight Fees apply: Other fees apply: No				
Other Data Information Demoired to Decree DO					
Other Data Information Required to Process PO:	Return Instructions				
Patient Procedure Date: Physician Name:	Contact # if product is received damaged: Is product returnable for credit: Yes				
Physician/Clinic Phone #	URL/Link to returns policy:				
Physician State License #	Special regulations or returns requirements for this product in certain states? Yes				
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?				
Physician/Clinic Specialty:	·				
Miscellaneous Notes:					
	ADDITIONAL INFORMATION				
	Is product order for scheduled patient procedure?				
	Is product order for restocking purposes?				