

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014			Intro	duction Type:	l	New Item		F	Final Version		Date:	5/19/	2015	
		PF	RODUCT INFORMATION						SPECIAL HA	NDLING AND S	TORAGE REQU	JIREMENTS*		
Company Name: Strides Pharma Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA, Med Device:			79128				, , , , , , , , , , , , , , , , , , ,	I. Freezer – between -25 and -10 C (-13° – 14° F)						
			nd Zidovudine Tablets USP 150 / 300mg								•	,		
NDC: 64380-707-03			DPC: 364380707035					II. Cold – between 2 and 8 C (36° – 46° F) III. Cool – between 8 and 15 C (46° – 59° F)						
CVX Code:	04300-707-03			MVX Code:	304300707033					,	,	° – 77° F)		
									IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)					
Description:	ablet with 'LZ' engraved on one side and break line on other side.					V. Avoid Excessive Heat – above 40 C (>104° F)								
Active ingredients: Lamivudine and Zidovudine										,)			
Active ingredients.		Lamivadine and	u zidovudine					VI. Other Temperature Range Requirement (write in)						
URL for Additional Produ	uct Information:							VII. No Requirement						
Address: 201 South Main Street, Ste 3			Address 2:					b. Contact for temperature excursion questions:						
City:	Lambertville. NJ 08530		State: NJ		Zip: 8530			Name: Nagesh Majeti						
Key Contact:	J B Davis		Email: sales@strides		•			Number: 609-773-5004						
Phone Number:	.,			Fax: (855) 228-9481				Is this product to be shipped to customers on ice?						
		FOR G	GENERIC DRUG PRODUCTS					Is this product to be shipped to customers on dry ice?						
L Oranga Bask Batinas	AD		II. Brand Name:		loto		1				,			
I. Orange Book Rating: III. Generic Equivalent fo	AB	Lamitudina and	II. Brand Name: Combivir Tablets and Zidovudine Tablets					c. Special regulations for product in certain states?						
III. Generic Equivalent io														
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							Special retu	ırns requirement	ts for this produc	xt?				
Does supplier meet DSC	SA definition of manu	facturer?	No DUNS:											
Is product exempt from DSCSA? No								d. Store prod	duct (unit of sal	le) upright?				
If yes, select exemption	on:							Protect pr	oduct (unit of s	ale) from light	?			
Other exemption - Wri										3				
			If Yes, was original product purchased direct from mfr?							1				
Is product repackaged? No Is product sold by manufacturer's exclusive distributor?			If Yes, was origina	al product purcl	hased direct from m	fr?		e. Shelf life:	24	I Months				
	facturer's exclusive di		-	al product purcl	hased direct from m	ifr?		e. Shelf life:	24 Initial shelf li	Months	different):		Months	
		stributor?	Yes		hased direct from m documentation fror			e. Shelf life:		Months ife at launch (if	different):		Months	
Is product sold by manu		stributor? e?	Yes	If yes, attach				e. Shelf life:	Initial shelf li	ife at launch (if	,		Months	
Is product sold by manu Are any waivers granted		stributor? e?	-	If yes, attach	documentation fror			e. Shelf life:	Initial shelf li	ife at launch (if	ORMATION	Volume	Months	
Is product sold by manu Are any waivers granted		stributor? e? ADDITIONAL P	Yes RODUCT INFORMATION	If yes, attach	documentation from			e. Shelf life:	Initial shelf li	PACKING INF	ORMATION nsmts.)	Volume (Cube)	Months # Pieces:	
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