

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014			intro	auction Type:	new item		F	inal Version		Date:	0/23/	2014	
			PRODUCT INFORMATION					SPECIAL HAI	NDLING AND S	TORAGE REQU	JIREMENTS*		
Company Name: Zydus Pharmaceuticals USA Inc. Application: ANDA						DA	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA, Med Device: 77-094				· ·				I. Freezer – between -25 and -10 C (-13° – 14° F)					
Rx Product/Proprietary Name: Ribavirin Tablets, 200 mg, 168 ct							II. Cold – between 2 and 8 C (36° – 46° F)						
					368382046031		III. Cool – between 2 and 3 C (36 – 46 P)						
CVX Code:	0000201000			MVX Code:	000002010001				,	,	° – 77° F)		
						la alain	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)						
Description: light pink to pink, round, biconvex, beveled, film-coated tablets debossed with the logo of 'ZC19' on one side, other side plain							V. Avoid Excessive Heat – above 40 C (>104° F)						
Active ingredients: Ribavirin							V. Avoid Excessive Real – above 40 C (5104 F) VI. Other Temperature Range Requirement						
TODATHII							(write in)						
URL for Additional Product Information: www.zydususa.com							v	/II. No Requiren	nent			1	
Address: 73 Route 31 North			Address 2:				b. Contact for temperature excursion questions:						
City:	Pennington		State: NJ Zip: 08534				Name:						
Key Contact:			Email:				Number:						
Phone Number: (609) 730 1900			Fax: (609) 730 1991				Is this product to be shipped to customers on ice?						
FOR GENERIC DRUG PRODUCTS							Is this product to be shipped to customers on dry ice?						
I. Orange Book Rating: AB II. Brand Name: Copegus												•	
III. Generic Equivalent for Brand: Ribavirin Tablets, 200 mg, 168 d				1 0			c. Special regulations for product in certain states?				No		
			AIN SECURITY ACT (DSCSA) INFORMATION				_	-	ts for this produc		No	•	
· · · · · · · · · · · · · · · · · · ·							Opediai reta	mo requirement	to for this produc		- 110	-	
Does supplier meet DSCSA definition of manufacturer? Yes DUNS: 156861945													
Is product exempt from DSCSA? No			_				d. Store product (unit of sale) upright? Yes				Yes	<u>.</u>	
If yes, select exemption:							Protect pro	oduct (unit of s	sale) from light?	?	No		
Other exemption - Wri	ite in:								<u></u>				
Is product repackaged? No			If Yes, was original product purchased direct from mfr?				e. Shelf life:	24	Months				
			_										
Is product sold by manu			No					Initial shelf li	ife at launch (if	different):		Months	
Is product sold by manu Are any waivers granted		le?	No No		documentation from FDA				`	•		Months	
		le?	No						ife at launch (if	•		Months	
		le?	No No		documentation from FDA		Weight I hs	ITEM AND	`	ORMATION	Volume		
Is the Product Legend Device?	for product ID/barcoo	ADDITIONAL No	No No PRODUCT INFORMATION Unit of Sale	ORDER INFOR	documentation from FDA		Weight Lbs.	ITEM AND	PACKING INF	ORMATION	Volume (Cube)	Months # Pieces:	
Are any waivers granted Is the Product Legend Device? State Control?	for product ID/barcoo	ADDITIONAL No No	No No No PRODUCT INFORMATION Unit of Sale x Bottle	ORDER INFOR	documentation from FDA	Item:	Weight Lbs.	ITEM AND	PACKING INF	ORMATION ismts.)			
Is the Product Legend Device? State Control? ARCOS reportable?	for product ID/barcoo	ADDITIONAL No No No	No No No PRODUCT INFORMATION Unit of Sale Bottle Box/Carton	ORDER INFOR What is the N	documentation from FDA RMATION IDC selling unit?		1	ITEM AND	PACKING INF nensions (US m Height	ORMATION esmts.) Width:	(Cube)		
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	for product ID/barcoo	NO NO NO	No No No No PRODUCT INFORMATION Unit of Sale	ORDER INFOR What is the N	documentation from FDA	Box/	1	ITEM AND	PACKING INF nensions (US m Height	ORMATION esmts.) Width:	(Cube)		
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	for product ID/barcoo	ADDITIONAL No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g.	RMATION IDC selling unit? . 1 Box of 10 Vials)	Box/ Carton:	79.63 G	Dim Depth	D PACKING INF mensions (US m Height	ORMATION usmts.) Width:	(Cube) 6.6154	# Pieces:	
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?	Direct Ship Item	NO NO NO	No N	ORDER INFOR What is the N	RMATION IDC selling unit? . 1 Box of 10 Vials)	Box/	1	ITEM AND	PACKING INF nensions (US m Height	ORMATION esmts.) Width:	(Cube) 6.6154		
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Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Cot Hazardous Material/Cyto Is Item If Unit Dose, is item bar cot hospital scanning?	Direct Ship Item Direct Ship Item Licit Direct Agent?	No No No No No No No No	No N	ORDER INFOR What is the N Each (Write-in, e.g. Minimum ord If Yes, how m	AMATION ADC selling unit? . 1 Box of 10 Vials) der quantity? Each Inner/Carton/Pack Case Other Product Informa	Box/ Carton: Case: Pallet: UPC:	79.63 G 5.98LBS Case: Carton:	Dim Depth 12.95 47.24	D PACKING INF mensions (US m Height 3.41	ORMATION (Semts.) Width: 1.94 8.7 39.37	(Cube) 6.6154 0 501.35925 89328.0576	# Pieces:	
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