



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	77224
Rx Product/Proprietary Name:	Ribavirin Capsules, 200 mg, 84 ct
NDC:	68382-260-12
UPC:	368382260123
CVX Code:	
MVX Code:	
Description:	White to off White granular powder filled in size '0' hard gelatin capsules with white colored cap printed with "ZA-12" in black ink & white colored body printed with "200mg" in black ink.
Active ingredients:	Ribavirin
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
Address 2:	
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
<b>e. Shelf life:</b>	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Rebetol Capsules
III. Generic Equivalent for Brand:	Ribavirin Capsules, 200 mg, 84 ct

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
DUNS:	156861945
Is product exempt from DSCSA?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Are any waivers granted for product ID/barcode?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Legend Device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
State Control?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
ARCOS reportable?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Co-Licensed?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Controlled Substance?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is it reverse numbered?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	3.97 G		3.97	2.21	8.7737	
Box/ Carton:					0	
Case:	2.21LBS	10.11	5	15.07	761.7885	24
Pallet:		47.24	48.83	39.37	90815.9286	63
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer? <input type="checkbox"/>	Size/Strength/Form:
<input type="text"/>	84ct/200mg/Capsule
(Write-in, e.g. 1 Vial)	Product Shape: Gelatin Capsule
Rx billing unit to pharmacy:	Product Color: White
<input checked="" type="checkbox"/> Each	Product Imprint: ZA-12 200mg
<input type="checkbox"/> Gram	
<input type="checkbox"/> Milliliter	

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$112.06	
As of date: <input type="text" value="9/10/2014"/>		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: