Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item | [ ] Final Version | **Date:** 5/5/2016

PRODUCT INFORMATION

Company Name: Zydus Pharmaceuticals USA Inc. | **Application:** ANDA

Application Number for NDA/ANDA/BLA, Med Device: 206747

Rx Product/Proprietary Name: Voriconazole Tablets, 200 mg 30 count

NDC: 68382-736-06 | **UPC:** 368382736062

CVX Code: | **MVX Code:**

Description: white to off-white, oval, biconvex, film-coated tablet debossed with “736” on one side and plain on the other side

Active ingredients: Voriconazole

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

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB | **II. Brand Name:** Vfend

III. Generic Equivalent for Brand: Voriconazole Tablets, 200 mg 30 count

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes | **DUNS:** 156861945

Is product exempt from DSCSA? No

If yes, select exemption:

Other exemption - Write in:

Is product repackaged? No | **If Yes, was original product purchased direct from mfr?**

Is product sold by manufacturer's exclusive distributor? No

Are any waivers granted for product ID/barcode? No | **If yes, attach documentation from FDA**

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

- [ ] I. Freezer – between -25 and -10 C (-13° – 14° F)
- [ ] II. Cold – between 2 and 8 C (36° – 46° F)
- [ ] III. Cool – between 8 and 15 C (46° – 59° F)
- [x] IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
- [ ] V. Avoid Excessive Heat – above 40 C (>104° F)
- [ ] VI. Other Temperature Range Requirement (write in)
- [ ] VII. No Requirement

b. Contact for temperature excursion questions:

Name:

Number:

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

c. Special regulations for product in certain states? No

Special returns requirements for this product? No

d. Store product (unit of sale) upright? Yes

Protect product (unit of sale) from light? No

e. Shelf life: 24 **Months**

Initial shelf life at launch (if different): **Months**

ADDITIONAL PRODUCT INFORMATION

Is the Product… Direct Ship Item

Legend Device? No

State Control? No

ARCOS reportable? No

Co-Licensed? No

Controlled Substance? No

Schedule No.?

(incl. N for non-narcotic)

Controlled Substance Code:

Hazardous Material/Cytotoxic Agent? No

Is Item...

If Unit Dose, is item bar coded to unit dose for hospital scanning?

Is it reverse numbered?

ORDER INFORMATION

	Unit of Sale
[x]	Bottle
[ ]	Box/Carton
[ ]	Ampule
[ ]	Glass
[ ]	Tube
[ ]	Vial Liquid Sgl
[ ]	Vial Liquid Multi
[ ]	Vial Powder Sql
[ ]	Vial Power Multi
[ ]	Other: Write In

What is the NDC selling unit? Each

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

	Each
	Inner/Carton/Pack
1	Case

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width:	Volume (Cube)	# Pieces:
Item:	45.95		2.982	1.609	4.798038	
Box/ Carton:					0	
Case:	3.67 lbs	3.82	9.72	6.5	241.3476	24
Pallet:	745 lbs	47	39	47	86151	198
UPC:	**Case:**					
	Carton:					

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

[x]	Each
[ ]	Gram
[ ]	Milliliter

Other Product Information

Size/Strength/Form: 30/200mg/Tablet

Product Shape: Oval

Product Color: white to off-white

Product Imprint: "736"

COST INFORMATION

Regular Cost Per Unit of Sale ($)	Invoice Cost (WAC) ($)	Federal Excise Tax Per Unit of Sale

As of date: 5/5/2016

WHOLESALER USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

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: