



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	204314
Rx Product/Proprietary Name:	Acyclovir tablets USP, 400mg 100ct
NDC:	68382-791-01
CVX Code:	
UPC:	3.68383E+11
MVX Code:	
Description:	white to off-white colored, round shaped, biconvex, uncoated tablets, debossed with "791" on one side and plain on the other side
Active ingredients:	Acyclovir
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Address 2:	
Email:	
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:	Zovirax
III. Generic Equivalent for Brand:	Acyclovir tablets USP, 400mg 100ct

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

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	<input checked="" type="checkbox"/> Bottle
Legend Device?	<input type="text" value="No"/>	What is the NDC selling unit?	each
State Control?	<input type="text" value="No"/>	(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
ARCOS reportable?	<input type="text" value="No"/>	Minimum order quantity?	<input type="text" value="Yes"/>
Co-Licensed?	<input type="text" value="No"/>	If Yes, how many of which package type?	<input type="text"/>
Controlled Substance?	<input type="text" value="No"/>	<input type="text"/>	Each
Schedule No.?	<input type="text"/>	<input type="text"/>	Inner/ Carton/Pack
(incl. N for non-narcotic)		<input type="text" value="1"/>	Case
Controlled Substance Code:	<input type="text"/>		
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/>		
Is Item...	<input type="text"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
Is it reverse numbered?	<input type="text"/>		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	84g		3.375	1.828	6.1695	
Box/ Carton:					0	
Case:	5.7	7.52	4.33	11.3	367.94608	24
Pallet:	753	47	39	47	86151	128
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>	Size/Strength/Form:	<input type="text" value="100/400mg/ Tablet"/>	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	Round		\$17.50	
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each	Product Color:	White to off white			
		<input type="checkbox"/> Gram		Product Imprint:	"791"			
		<input type="checkbox"/> Milliliter						

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$17.50	
As of date: <input type="text" value="4/28/2015"/>		

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:



# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No  
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No  
RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  
 (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);  
SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	Item	2D	Linear	<input type="checkbox"/>	10368382791013
If not, when?	<input type="text"/>	Box/Carton	2D	Linear	<input type="checkbox"/>	
Items aggregated to case?	<input type="text"/>	Case	2D	Linear	<input type="checkbox"/>	
		Pallet	2D	Linear	<input type="checkbox"/>	

## REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

## ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic  Inorganic

Antineoplastic  Steroid/Androgen

Corrosive  Oxidizer

Aerosol Class; Identify NFPA Storage Level:

## RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

## ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

## CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

## MISCELLANEOUS NOTES and/or Image of Product Barcode:





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Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	204314
Rx Product/Proprietary Name:	Acyclovir tablets USP, 400mg 500ct
NDC:	68382-791-05
CVX Code:	
UPC:	3.68383E+11
MVX Code:	
Description:	white to off-white colored, round shaped, biconvex, uncoated tablets, debossed with "791" on one side and plain on the other side
Active ingredients:	Acyclovir
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Address 2:	
Email:	
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 checked="" type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input 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:	Zovirax
III. Generic Equivalent for Brand:	Acyclovir tablets USP, 400mg 500ct

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

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	What is the NDC selling unit? <input type="text" value="each"/>
Legend Device?	<input type="text" value="No"/>	<input type="checkbox"/> Bottle	
State Control?	<input type="text" value="No"/>	<input type="checkbox"/> Box/Carton	
ARCOS reportable?	<input type="text" value="No"/>	<input type="checkbox"/> Ampule	
Co-Licensed?	<input type="text" value="No"/>	<input type="checkbox"/> Glass	
Controlled Substance?	<input type="text" value="No"/>	<input type="checkbox"/> Tube	
Schedule No.?	<input type="text"/>	<input checked="" type="checkbox"/> Vial Liquid Sgl	
(incl. N for non-narcotic)		<input type="checkbox"/> Vial Liquid Multi	
Controlled Substance Code:	<input type="text"/>	<input type="checkbox"/> Vial Powder Sgl	
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/>	<input type="checkbox"/> Vial Power Multi	
Is Item...	<input type="text"/>	<input type="checkbox"/> Other: Write In	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	Minimum order quantity? <input type="text" value="Yes"/>	
Is it reverse numbered?	<input type="text"/>	If Yes, how many of which package type?	
		<input type="text"/>	Each
		<input type="text" value="1"/>	Inner/ Carton/Pack
			Case

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	315.45g		5.06	3.16	12	
Box/ Carton:					0	
Case:	10.03	9.65	6.02	12.87	747.65691	12
Pallet:	619	47	39	47	86151	60
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="text"/>	Size/Strength/Form: <input type="text" value="500/400mg/ Tablet"/>
(Write-in, e.g. 1 Vial)	Product Shape: <input type="text" value="Round"/>
Rx billing unit to pharmacy:	Product Color: <input type="text" value="White to off white"/>
<input checked="" type="checkbox"/> Each	Product Imprint: <input type="text" value="791"/>
<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
	\$85.00	
As of date: <input type="text" value="4/28/2015"/>		

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:



# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen  
 Reproductive Toxicant  
 Both  
 Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions?  
 (If yes, attach SDS with special instructions.) No

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No  
 RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  
 (if yes, identify method below)

Limited Quantity  
 Consumer Commodity, ORM-D  
 Small Quantity (49 CFR 173.4)  
 Special Permit; DOT-SP  
 Special Provision (listed in Column 7 of 49 CFR 172.101);  
 SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger  
 Cargo  
 Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	Item	2D	Linear	<input type="checkbox"/>	10368382791051
If not, when?	<input type="text"/>	Box/ Carton	2D	Linear	<input type="checkbox"/>	
Items aggregated to case?	<input type="text"/>	Case	2D	Linear	<input type="checkbox"/>	
		Pallet	2D	Linear	<input type="checkbox"/>	

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	<u>No</u>
If Yes, is it managed with a pharmacy registry?	<input type="text"/>
Website URL:	<input type="text"/>
Comments / Details: (For example, iPledge program?)	
<input type="text"/>	

**ADD'L STORAGE INFORMATION**

Please check as appropriate for this product.

Organic  Inorganic  
 Antineoplastic  Steroid/Androgen  
 Corrosive  Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<u>877-993-8779</u>
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	<u>www.zydususa.com</u>
Special regulations or returns requirements for this product in certain states?	<u>No</u>
If so, which states? Other requirements? Comments?	<input type="text"/>

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine  
 Pseudoephedrine  
 Phenylpropanolamine  
 Iodine (≥2.2%)  
 Other:

**CLASS OF TRADE RESTRICTION:**

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

**ADDITIONAL INFORMATION**

If Unit Dose NDC, indicate NDC here:

**MISCELLANEOUS NOTES and/or Image of Product Barcode:**

