



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 (drug); PMA/510(k)(med device):	207758
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	ETHACRYNATE SODIUM INJ 50MG
Selling Unit NDC:	68382-246-01
Individual Unit NDC:	
UPC:	368382246011
UDI	
CVX Code:	
MVX Code:	
Description:	white to off-white lyophilized powder or cake. It is supplied in vials containing ethacrynate sodium equivalent to 50 mg of ethacrynic acid.
Active Ingredient(s):	ETHACRYNATE
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
Fax:	(609) 730 1998
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77°)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	
Number:	
Group E-mail:	
c. Special regulations for product in any states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product... Neither	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION	
Size:	1 VIAL
Strength:	50MG
Dosage Form:	IV Injection
Product Shape:	N/A
Product Color:	WHITE TO OFF WHITE
Product Imprint:	N/A

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit? □
<input type="checkbox"/> Bottle	1 box of 1 vial
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? Yes
<input type="checkbox"/> Tube	
<input checked="" type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="checkbox"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> Inner/ Carton/Pack
<input type="checkbox"/> Vial Power Multi	<input type="text" value="1"/> Case
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	EDECIN

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer? □	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:		1.69	2.84	1.69	8.111324	1
Box/Carton/Bundle/Inner Pack:	0.01	1.96	3.35	1.96	12.86936	1
Case:	6.61	7.48	6.69	8.66	433.356792	24
Pallet:	853	48	40	48	92160	2880
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
				2D	Linear	Quantity
No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	<input checked="" type="checkbox"/>	Linear	00368382246011
If not, when?	<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack			<input checked="" type="checkbox"/>	Linear	
Items aggregated?	<input checked="" type="checkbox"/> Case		24	<input checked="" type="checkbox"/>	Linear	40368382246019
Yes	<input checked="" type="checkbox"/> Pallet			<input checked="" type="checkbox"/>	Linear	80368382246017
				<input type="checkbox"/>	Linear	
				<input type="checkbox"/>	Linear	
				<input type="checkbox"/>	Linear	
				<input type="checkbox"/>	Linear	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$3,800.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	5/29/2018		

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: