



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):	206228
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	ARSENIC TRIOXIDE INJECTION 10MG/10ML (10X10ML SD VIALS)
Selling Unit NDC:	68382-997-10
Individual Unit NDC:	
UPC:	368382997104
UDI	
CVX Code:	
MVX Code:	
Description:	sterile, clear, colorless solution in 10 mL glass, single-dose vials
Active Ingredient(s):	ARSENIC TRIOXIDE
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Address 2:	
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?	<input type="checkbox"/>
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/>
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 <input type="checkbox"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	Yes <input type="checkbox"/>
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months <input type="checkbox"/>

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

PRODUCT DESCRIPTION INFORMATION	
Size:	10 X 10 SD VIALS
Strength:	10MG/10mL
Dosage Form:	SD VIAL
Product Shape:	NA
Product Color:	CLEAR, COLORLESS
Product Imprint:	NA

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

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

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

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.07	0.98	1.97	0.98	1.891988	1
Box/Carton/Bundle/Inner Pack:	0.83	2.05	2.4	5.12	25.1904	10
Case:	9.92	10.8	5.6	6.7	405.216	12
Pallet:	651.98	48	36	40	69120	768
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
If not, when? <input type="text" value="12/1/2018"/>	<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	1	00368382997104		
Items aggregated? <input type="checkbox"/>	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	12	40368382997102		
	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		50368382997109		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$5,415.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	12/10/2018		