



# 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 Number for NDA/ANDA/BLA, Med Device:	202360
Rx Product/Proprietary Name:	Etomidate Injection, USP, 20mg/10ml (2mg/ml)
NDC:	68382-545-07
CVX Code:	
UPC:	368382545077
MVX Code:	
Description:	Supplied in single-dose containers
Active ingredients:	Etomidate
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
Key Contact:	
Phone Number:	(609) 730 1900
Address 2:	
State:	NJ
Zip:	08534
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?	No
Is this product to be shipped to customers on dry ice?	No
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	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:	AP
II. Brand Name:	Amidate
III. Generic Equivalent for Brand:	Etomidate Injection, USP, 20mg/10ml (2mg/ml)

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:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>
Legend Device?	No
State Control?	No
ARCOS reportable?	No
Co-Licensed?	No
Controlled Substance?	No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	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"/>

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	23g		1.772	0.945	1.67454	
Box/ Carton:		5.118	2.047	2.205	23.1007839	10
Case:	15.3	7.48	8.858	10.709	709.555209	24
Pallet:						
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?	Size/Strength/Form:
<input type="text"/>	10ml/2mg/IV injection
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	N/A
<input type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	Clear Colorless
<input checked="" type="checkbox"/> Milliliter	Product Imprint:
	N/A

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$62.20	
As of date: <input type="text"/>		

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:



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PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application Number for NDA/ANDA/BLA, Med Device:	202360
Rx Product/Proprietary Name:	Etomidate Injection, USP, 40mg/20ml (2mg/ml)
NDC:	68382-545-08
CVX Code:	
UPC:	368382545084
MVX Code:	
Description:	Supplied in single-dose containers
Active ingredients:	Etomidate
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
Key Contact:	
Phone Number:	(609) 730 1900
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Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	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"/>

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Box/ Carton:	42g		2.165	1.181	2.556865	
Case:	13.45	5.906	8.858	14.094	737.332515	12
Pallet:						
UPC:	Case:	<input type="text"/>				
	Carton:	<input type="text"/>				

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?	Size/Strength/Form:
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(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	N/A
<input type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	Clear Colorless
<input checked="" type="checkbox"/> Milliliter	Product Imprint:
	N/A

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
<input type="text"/>	\$67.20	<input type="text"/>
As of date: <input type="text"/>		

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

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