



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: Post Launch Change

Final Version

Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name:	<input type="text" value="Zydus Pharmaceuticals USA Inc."/>	Application:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA, Med Device:	<input type="text" value="75-395"/>		
Rx Product/Proprietary Name:	<input type="text" value="Isosorbide Mononitrate Extended-Release Tablets, 120 mg 100s"/>		
NDC:	<input type="text" value="68382-652-01"/>	UPC:	<input type="text" value="368382652010"/>
CVX Code:	<input type="text"/>	MX Code:	<input type="text"/>
Description:	<input n120"="" on="" one="" side"="" type="text" value="oval, w white, film-coated tablets, debossed "/>		
Active ingredients:	<input type="text" value="Isosorbide mononitrate"/>		
URL for Additional Product Information:	<input type="text" value="www.zydususa.com"/>		
Address:	<input type="text" value="73 Route 31 North"/>	Address 2:	<input type="text"/>
City:	<input type="text" value="Pennington"/>	State:	<input type="text" value="NJ"/>
Key Contact:	<input type="text"/>	Email:	<input type="text"/>
Phone Number:	<input type="text" value="(609) 730 1900"/>	Fax:	<input type="text" value="(609) 730 1991"/>
		a. Temperature – Indicate the USP temperature range for this product. <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 (w rite in) <input type="text"/> <input type="checkbox"/> VII. No Requirement	
		b. Contact for temperature excursion questions: 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"/>	

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:	<input type="text" value="AB"/>	II. Brand Name:	<input type="text" value="Imdur"/>
III. Generic Equivalent for Brand:	<input type="text" value="Isosorbide Mononitrate Extended-Release Tablets, 120 mg 100s"/>		

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

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

c. Special regulations for product in certain states?	<input type="text" value="No"/>
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	<input type="text" value="Yes"/>
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text"/> Months

ADDITIONAL PRODUCT INFORMATION

Is the Product... Direct Ship Item	<input type="checkbox"/>
Legend Device?	<input type="checkbox"/> No
State Control?	<input type="checkbox"/> No
ARCOS reportable?	<input type="checkbox"/> No
Co-Licensed?	<input type="checkbox"/> No
Controlled Substance?	<input type="checkbox"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="checkbox"/> 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 checked="" type="checkbox"/> Bottle
	<input type="checkbox"/> Box/Carton
	<input type="checkbox"/> Ampule
	<input type="checkbox"/> Glass
	<input type="checkbox"/> Tube
	<input type="checkbox"/> Vial Liquid Sgl
	<input type="checkbox"/> Vial Liquid Multi
	<input type="checkbox"/> Vial Powder Sgl
	<input type="checkbox"/> Vial Powder Multi
	<input type="checkbox"/> Other: Write In
What is the NDC selling unit?	<input type="text" value="Each"/>
(Write-in, e.g. 1 Box of 10 Vials)	
Minimum order quantity?	<input type="checkbox"/> Yes
If Yes, how many of which package type?	<input type="text"/>
	<input type="text"/>
	<input type="text" value="1"/>

ITEM AND PACKING INFORMATION

Item	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	52.65 g		3.23	1.77	5.7171	
Box/Carton:					0	
Case:	2.85	11.06	4.18	7.5	346.731	24
Pallet:		48	40	51	97920	220
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"/>	<input type="text" value="100ct/120mg/Tablets"/>
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	<input type="text" value="Oval"/>
<input checked="" type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	<input type="text" value="White"/>
<input type="checkbox"/> Milliliter	Product Imprint:
	<input type="text" value="N 120"/>

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$60.75	
As of date: <input type="text" value="6/26/2015"/>		

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)

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

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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#

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

Passenger

Cargo

Passenger & Cargo

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

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 PRODUCT INFORMATION - Serialization

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

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?)

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?

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> _____ b. Autofax <input type="checkbox"/> _____ Fax Number: _____ c. Fax <input type="checkbox"/> _____ Fax Number: _____ d. Phone only <input type="checkbox"/> _____ Phone No.: _____ e. Supplier Web Site only <input type="checkbox"/> _____ Site Address: _____ Minimum Order Quantity: _____ Supplier's Customer Service Number: _____ Contracted 3PL company / contact #: _____ Name: _____ Phone: _____	Purchase order daily receipt cut off time by supplier Cut off time: _____ Shipping lead time of PO: _____ Hours _____ Days Ships same day for next day receipt: _____ Ships for second day receipt: _____ Ships regular ground for 3-10 days receipt: _____
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: _____ Drop Ship service fee billed with each order: _____ Drop Ship miscellaneous fees billed: _____ Comments: _____	Overnight receipt available: _____ PO Receipt cut off time: _____ Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: _____ PO Receipt Cut off time: _____ Saturday Overnight receipt available: _____ PO Receipt Cut off time: _____ Order receipt method: Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ Overnight Fees apply: _____ Other fees apply: _____
Class of Trade Restriction:	REMS or Registry Restrictions
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices _____ Restricted to retail pharmacy only: _____ Restricted to hospital, clinics, and physician offices only: _____ Restricted from US territories? (explain in comments) _____ Comments: _____	REMS: _____ REMS Program Manager Name: _____ Phone: _____ Supplier Manages REMS registry exclusively: _____ Wholesale distributor support: _____ Provider Name: _____ Site Enrollment Number assigned by Supplier: _____ DEA #: _____ PCPDP #: _____ NPI #: _____ Comments: _____ Registry: _____ Registry Program Contact Name: _____ Phone: _____ Comments: _____
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____	Contact # if product is received damaged: _____ Is product returnable for credit: _____ URL/Link to returns policy: _____ Special regulations or returns requirements for this product in certain _____ If so, which states? Other requirements? Comments? _____
Miscellaneous Notes:	ADDITIONAL INFORMATION
_____ _____ _____	Is product order for scheduled patient procedure? _____ Is product order for restocking purposes? _____