



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application Number for NDA/ANDA/BLA, Med Device:	89-884
Rx Product/Proprietary Name:	NITROGLYCERIN TRANSDERMAL SYSTEMS, 0.2MG/HR
NDC:	68382-309-30
CVX Code:	
UPC:	368382309303
MVX Code:	
Description:	NITROGLYCERIN TRANSDERMAL SYSTEM 0.2 MG/HR
Active ingredients:	NITROGLYCERIN
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

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
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 (write 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?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain 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:	
<input type="text" value="36"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB2
II. Brand Name:	NITROGLYCERIN TRANSDERMAL SYSTEMS 0.2MG/HR
III. Generic Equivalent for Brand:	TRANSDERM NITRO

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:	
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	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>
Legend Device?	No
State Control?	<input type="text"/>
ARCOS reportable?	<input type="text"/>
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... Unit Dose	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	Yes
Is it reverse numbered?	No

ORDER INFORMATION	
Unit of Sale	<input checked="" type="checkbox"/> Box/ Carton
What is the NDC selling unit?	1 Shelf Carton of 30 patches
(Write-in, e.g. 1 Box of 10 Vials)	
Minimum order quantity?	Yes
If Yes, how many of which package type?	
<input type="text" value="24"/> 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:		
Item:	0.0055	2.56	2.56		0	1
Box/ Carton:	0.1667	2.75	2.75	1.375	10.3984375	30
Case:	4	11.625	3.25	8.5	321.140625	24
Pallet:	680	48	53	40	101760	170
UPC:	Case:					
	Carton:	368382309303				

PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer?	1 Shelf Carton of 30 patches	Size/Strength/Form:	0.2mg/hr patch
(Write-in, e.g. 1 Vial)		Product Shape:	
Rx billing unit to pharmacy:		Product Color:	
<input type="checkbox"/> Each		Product Imprint:	Nitroglycerin 0.2mg/hr
<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
	\$21.19	
As of date: <input type="text" value="2/14/2017"/>		

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<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: