

Standard Pharmaceutical Product Information (Rx Product Only)

Company Name	© August 2014 Introduction Type: New Item								x Fir	nal Version		Date:	1/11/	2017	
Application Number for IDA/AND/AND/AND/AND/AND/AND/AND/AND/AND/A	PRODUCT INFORMATION								:	SPECIAL HAN	IDLING AND ST	ORAGE REQU	IREMENTS*		
Application Number for 190A/ARDA/ARDA/ARD At Note Device: 19935 NF Product/Property Names MTROGUYCERN PANSDERNA, SYSTEMS 0.4455458 NF Votable Production Note N	Company Name: Zvdus Pharmaceuticals USA Inc. Application:								a. Temperature	- Indicate the	USP temperat	ure range for th	is product.		
NOC CVX Code									41 						
Control of Source Not Control of Source So	Rx Product/Proprietary N	Name:	NITROGLYCE	RIN TRANSDERMAL SYS	TEMS 0.4MG/HF	?			x II.	Cold – between	n 2 and 8 C (36°	– 46° F)			
Best STROCK VERNIT RANSDERMAN SYSTEM 0.4 MGHR			•								•	,			
Active ingredients: URL for Additional Product Information: WW.2503UBBACOTT W									IV.	Controlled Ro	om – between 2	0 and 25 C (68°	– 77° F)		
Active ingredients: NITCGLYCERN	Description: NITROGLYCERIN TRANSDERMAL SYSTEM 0.4 MG/HR											•	•		
Marked product information: Www.ydukasa.com	Active ingredients: NITROGLYCERIN											, ,			
Address: File Address File Address File Address File Address File File Address File Fi	LIPI for Additional Product Information:									,	ent				
State September State State September State September Septembe									·	•		ons.			
Number:															
Phone Number: (509) 730 1980	=														
I. Crange Book Rating: AB2 I. Brand Name: NTROGLYCERIN TRANSDERMAL SYSTEMS 0.4MG/HR No DRUGS UPPLY CHAIN SEQURITY ACT (DSCSA) INFORMATION DOES supplier meet DSCSA definition of manufacturer? YES DUNS: [158851945] If yes, select exemption: Other exemption Write in: Is product exemption Write in: Is product repedual distributior? No If Yes, was original product purchased direct from mfr? Yes No If Yes, was original product purchased direct from mfr? Yes No If Yes, select exemption: Other exemption Write in: Is the Product sold by manufacturer's exclusive distributior? No If Yes, was original product purchased direct from mfr? Yes No If Yes, was original product purchased direct from mfr? Yes No If Yes, attach documentation from FDA It the Product in Other Product (Unit of sale) upright? Yes Initial shell file at launch (I different): Months **Months** **Months** **Acon washing spracted for product (Unit of sale) upright? Yes Is the Product sold by manufacturer's exclusive distributior? No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased direct from mfr? **No If Yes, was original product purchased				Fax: (609) 730 1991											
ITEMSSDERM NITRO			FOR	GENERIC DRUG PRODU	СТЅ				Is this produc	t to be shipped	to customers or	n dry ice?	No		
It Cenaric Equivalent for Brand: TEANSDERM NITRO TOUGH SUPPLY CHAIN SECURITY ACT (OSGS) INFORMATION TEM AND FORMATION	I. Orange Book Rating: AB2 II. Brand Name: NITROGLYCERIN TRANSDERMAL SYSTEMS 0.4MG/HR												_		
Does supplier meet DSCSA definition of manufacturer? YES DUNS: 156861945		r Brand:	TRANSDERM						c. Special regulations for product in certain states?						
Does supplier meet DSCSA definition of manufacturer? YES DUNS: 156861945		DRI	JG SUPPLY CH	AIN SECURITY ACT (DSC	SA) INFORMATI	ON			Special return	s requirements	for this product	?	No		
Sproduct exempt from DSCSA? No									-,		, , , , , , , , , , , , , , , , , , , ,				
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive distributor? Yes No If yes, ast and documentation from FDA If yes, ast and documenta				163					d. Store produ	ct (unit of sale	e) upright?		Yes		
Second control of Substance Code: Hazardous Material/Cytotoxic Agent? No If yes, was original product purchased direct from mfr? State Control of Substance Code: Hazardous Material/Cytotoxic Agent? No Size Control of Substance Code: Hazardous Material/Cytotoxic Agent? No Size Control of Substance Code: Hazardous Material/Cytotoxic Agent? No Size Control of Substance Code: Hazardous Material/Cytotoxic Agent? No Size Control of Substance Code: Hazardous Material/Cytotoxic Agent? No Size Control of Substance Code: Hazardous Material/Cytotoxic Agent? No Size Control of Substance Code: Hazardous Material/Cytotoxic Agent? No Size Control of Substance Code: Size Co									_	-					
Is product repackaged? Is product sold by manufacturer's exclusive distributor? Yes No If yes, attach documentation from FDA Yes No								i Totect prod	iuci (uniii or se	ile) iroin ligitt:		140			
Second to decide by manufacturer's exclusive distributor? No If yes, attach documentation from FDA									e Shelf life:	36	Months				
Ace any waivers granted for product ID/barcode?									e. onen me.			different):		Months	
State Control? State Control of Stat											(
Legend Device? No State Control? Bottle State Control? ARCOS reportable? Shelf Carton of 30 patches Show Carton Ampule Shelf Carton of 30 patches Show Carton Shelf Carton of 30 patches Show Carton Shelf Carton of 30 patches Show Carton Show Carto										ITEM AND	PACKING INFO	DRMATION			
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State Control? ARCOS reportable? Co-Licensed? No Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Liquid Multi Vial Powder Sgl Vial Powder S								Weight Lbs.		=	-		# Pieces:		
ARCOC Feportable?	_			Bottle			ltom.	0.006043333					1		
Controlled Substance? Schedule No.? (incl. Nfo non-narcotic) (incl. Nfo non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered? No PHARMACY ORDER / BILL UNIT Other Product Information Size/Strength/Form: [1 Sheff Carton of 30 patches] Wholesaler Use ONLY: Vendor #: Whish. Code #: Fineline Code: Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. Minimum order quantity? Yes Minimum order quantity? Yes Which is quantity? Yes Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Each Other: Write In Other Product Information Case: 5 11.625 3.5625 9.5 393.433594 24 Pallet: 800 48 53 40 101760 160 Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC: Case: UPC:	1			x Box/Carton	·				0.000943333	2.075	2.675		U	'	
Schedule No.? [(incl. N for non-narcotic)] Controlled Substance Code: [Incl. N for non-narcotic)] Controlled Substance Code: [Incl. N for non-narcotic)] Controlled Substance Code: [Incl. N for non-narcotic)] Is Item Unit Dose [Incl. N for non-narcotic)] Incl. N for non-narcotic [Incl. N for non-narcotic)] Incl. N for non-narcotic) Incl. N for non-narcotic [Incl. N for non-narcotic)] Incl. N for non-narcotic) Incl. N for non-narcotic [Incl. N f					(Write-in, e.g	. 1 Box of 10 Vials)			0.2083	3.0625	3.0625	1.375	12.8959961	30	
Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Liquid Multi Vial Powder Sql Vial Liquid Multi Vial Powder Sql Vial Liquid Multi Vial Powder Multi Other: Write In If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered? Is it reverse numbered? WHOLESALER USE ONLY: WHOLESALER USE ONLY	Schedule No.?		110	Tube Minimum ord		der quantity? Yes Yes			5	11.625	3.5625	9.5	393.433594	24	
Hazardous Material/Cytotoxic Agent? Is Item Unit Dose If Unit Dose, is item bar coded to unit dose for hospital scanning? Yes PHARMACY ORDER / BILL UNIT Is it reverse numbered? No Rec. sell unit to customer? I Shelf Carton of 30 patches WHOLESALER USE ONLY: Vendor #: Whsl. Code #: Fineline Code: Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.	,	•			If Yee how m	anne of subjets meakage tumo?									
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1 Shelf Carton of 30 patches O.4mg/hr patch Sale (\$)									Barrelan Cast	Dan Unit of			Fodoral Evoice Tay Box		
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Whsl. Code #: Fineline Code: Code #: Code #: Fineline Code:						•					\$2	4 49			
Fineline Code: Gram Milliliter Mitroglycerin 0.4 mg/hr As of date: 2/14/2017 Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.				l ——							Ψ ∠+.4 3				
Milliliter As of date: 2/14/2017 Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.				l ———		Product Imprint: Nitroalvcerin 0.4 ma/hr									
											As of date:	2/14/2017	<u> </u>		
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:			Attach copy of SA	AFETY DATA SHEET (SDS	S) or non hazard	letter, PACKAGE INSERT, LA	BEL AN	ID PHOTO (OF PRODUCT PAC	CKAGING and	BARCODE.			<u> </u>	