



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date: 9/29/16

PRODUCT INFORMATION				
Company Name:	AvKARE, INC		Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	86-923			
Rx Product/Proprietary Name:	Isosorbide Dinitrate 5mg Tablet UD50			
NDC:	50268-0447-15	UPC:		
CVX Code:		MXV Code:		
Description:	Isosorbide Dinitrate 5mg Tablet UD50			
Active Ingredients:				
URL for Additional Product Information:				
Address:	615 North First Street	Address 2:		
City:	Pulaski	State:	TN	
Key Contact:	Kim Bracey	Email:	kbracey@avkare.com	
Phone Number:	931-908-0028	Fax:	931-292-6229	
Zip:	38478			

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="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	_____
Number:	_____
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"/>	
c. Special regulations for product in certain states?	
Special returns requirements for this product? <input type="checkbox"/>	
d. Store product (unit of sale) upright? <input type="checkbox"/>	
Protect product (unit of sale) from light? <input type="checkbox"/>	
e. Shelf life: _____ Months	
Initial shelf life at launch (if different): _____ Months	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Isordil
III. Generic Equivalent for Brand:	Isosorbide Dinitrate

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
DUNS:	796560394
Is product exempt from DSCSA?	No
If yes, select exemption:	_____
Other exemption - Write in:	_____
Is product repackaged?	Yes
If Yes, was original product purchased direct from mfr?	Yes
Is product sold by manufacturer's exclusive distributor?	Yes
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	_____

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION		ITEM AND PACKING INFORMATION	
Is the Product...	Direct and Drop Ship	Unit of Sale	What is the NDC selling unit?	Weight Lbs.	Dimensions (US msmts.)
Legend Device?	No	Bottle	50 pills per box	Depth	Height
State Control?	No	Box/Carton	10 boxes per case	Width:	Volume (Cube)
ARCOS reportable?	No	Ampule	(Write-in, e.g. 1 Box of 10 Vials)	Item:	# Pieces:
Co-Licensed?	No	Glass		Box/	
Controlled Substance?	No	Tube	Minimum order quantity? Yes	Carton:	
Schedule No.?	No	Vial Liquid Sgl		Case:	
(incl. N for non-narcotic)		Vial Liquid Multi		Pallet:	
Controlled Substance Code:		Vial Powder Sgl		UPC:	
Hazardous Material/Cytotoxic Agent?	No	Vial Powder Multi		Case:	
Is Item...	Unit Dose	Other: Write In		Carton:	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	Yes				
Is it reverse numbered?	No				
WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		COST INFORMATION	
Vendor #:		Rec. sell unit to customer?	Size/Strength/Form:	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)
Whsl. Code #:		(Write-in, e.g. 1 Vial)	50ct/5mg/ Tablet		
Fineline Code:		Rx billing unit to pharmacy:	Product Shape:		
		Each	round		
		Gram	white		
		Milliliter	Product Imprint:		
			Par;020		
				As of date: 9/29/16	

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: _____