© August 2014		Introduction Type: New Item					Fi	nal Version		Date:	9/2	9/16	
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Company Name: AvKARE, INC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA, Med Device: 86-923							I. Freezer – between -25 and -10 C (-13° – 14° F)						
Rx Product/Proprietary Name: Isosorbide Dinitrate 5mg Tablet UD50							II. Cold – between 2 and 8 C (36° – 46° F)						
NDC: 50268-0447-15 UPC:							III. Cool – between 8 and 15 C (46° – 59° F)						
CVX Code: MVX Code:							x IV	/. Controlled R	oom – between	20 and 25 C (6	8° – 77° F)		
Description:	Isosorbide Dinitrate	5mg Tablet UD5)				allows for excursions between 15 and 30 C (59° – 86° F) V. Avoid Excessive Heat – above 40 C (>104° F)						
Active ingredients:								I. Other Tempe	erature Range I		F)	7	
URL for Additional Product Information:						(write in) VII. No Requirement							
Address: 615 North First Street			Address 2:				b. Contact for temperature excursion questions:						
City:	Pulaski		State:	TN	Zip: 38478		Name:						
Key Contact:	Kim Bracey		Email:	kbracey@av			Number:						
Phone Number:	Phone Number: 931-908-0028		Fax: 931-292-6229		9	Is this product to be shipped to customers on ice?							
		FOR	R GENERIC DRUG PRODUC	CTS			Is this produc	ct to be shippe	ed to customer:	s on dry ice?			
I. Orange Book Rating:	AB		II. Brand Name:	Isordil									
III. Generic Equivalent for Brand: Isosorbide Dir			nitrate				c. Special regu	lations for pro	oduct in certai	n states?			
	DRI	UG SUPPLY CH	AIN SECURITY ACT (DSCSA) INFORMATION				Special return	ns requirement	ts for this produ	uct?			
Does supplier meet DSC	SA definition of manu	facturer?	Yes	DUNS:	796560394		Ī					_	
Is product exempt from DSCSA? No			<u>_</u>				d. Store produ	ct (unit of sale	e) upright?			_	
If yes, select exemption:							Protect prod	duct (unit of s	ale) from light	?			
Other exemption - Wri	ite in:											_'	
Is product repackaged?		Yes	If Yes, was origin	nal product pure	chased direct from mfr?	Yes	e. Shelf life:		Months				
Is product sold by manuf			Yes		_			Initial shelf I	ife at launch (i	f different):		Months	
Are any waivers granted													
	i for product ib/barcoc		No		n documentation from FDA							_	
	Tor product 1D/barcot		No PRODUCT INFORMATION	, ·				ITEM AND	PACKING INF	ORMATION		•	
Is the Product	Direct and Drop Ship	ADDITIONAL	PRODUCT INFORMATION	ORDER INFOR	RMATION		Weight I be		PACKING INF		Volume	# Pieces:	
Legend Device?		ADDITIONAL No	PRODUCT INFORMATION Unit of Sale	ORDER INFOR	RMATION NDC selling unit?		Weight Lbs.				Volume (Cube)	# Pieces:	
Legend Device? State Control?		ADDITIONAL No No	Unit of Sale Bottle	ORDER INFOR	RMATION NDC selling unit?	Item:	Weight Lbs.	Dim	ensions (US n	ısmts.)		# Pieces:	
Legend Device? State Control? ARCOS reportable?		No No No	Unit of Sale Bottle x Box/Carton	ORDER INFORMATION What is the 150 pills per bit 10 boxes per	RMATION NDC selling unit?			Dim Depth	ensions (US m Height	nsmts.) Width:			
Legend Device? State Control? ARCOS reportable? Co-Licensed?		No No No No	Unit of Sale Bottle Box/Carton Ampule	ORDER INFORMATION What is the 150 pills per bit 10 boxes per	RMATION NDC selling unit?	Box/		Dim Depth	ensions (US m Height	nsmts.) Width:			
Legend Device? State Control? ARCOS reportable?		No No No	Unit of Sale Bottle x Box/Carton	ORDER INFOI What is the I 50 pills per b 10 boxes per (Write-in, e.4)	RMATION UDC selling unit? ox case J. 1 Box of 10 Vials)	Box/ Carton:	0.5	Dim Depth 2.00"	ensions (US n Height 4.25"	width:		1	
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcol	Direct and Drop Ship	No No No No	Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl	ORDER INFORMATION What is the last state of the	RMATION NDC selling unit? ox case g. 1 Box of 10 Vials) der quantity? Yes	Box/		Dim Depth	ensions (US m Height	nsmts.) Width:			
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcof Controlled Substance Co	Direct and Drop Ship	No No No No No	PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFORMATION What is the last state of the	RMATION NDC selling unit? ox case1 Box of 10 Vials) der quantity? Yes many of which package type?	Box/ Carton:	0.5	Dim Depth 2.00"	ensions (US n Height 4.25"	width:		1	
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcol	Direct and Drop Ship	No No No No	PRODUCT INFORMATION Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	ORDER INFORMATION What is the last state of the	RMATION NDC selling unit? ox case 3.1 Box of 10 Vials) der quantity? Yes many of which package type? Each	Box/ Carton: Case: Pallet:	0.5	Dim Depth 2.00"	ensions (US n Height 4.25"	width:		1	
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Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co Hazardous Material/Cyto	Direct and Drop Ship tic) dde: toxic Agent? Unit Dose	No No No No No	PRODUCT INFORMATION Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Sgl Vial Liquid Sgl Vial Power Multi Vial Power Multi	ORDER INFORMATION What is the last state of the	RMATION NDC selling unit? ox case j. 1 Box of 10 Vials) der quantity? Tyes many of which package type? Each Inner/Carton/Pack	Box/ Carton: Case: Pallet:	0.5 5	Dim Depth 2.00"	ensions (US n Height 4.25"	width:		1	
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