Standard Pharmaceutical Product Information (Rx Product Only)

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: 87-537
Rx Product/Proprietary Name: Isosorbide Dinitrate 20mg Tablet UD50
NDC: 50268-0449-15 **UPC:**
CVX Code: **MVX Code:**
Description: Isosorbide Dinitrate 20mg Tablet UD50
Active ingredients:
URL for Additional Product Information:
Address: 615 North First Street **Address 2:**
City: Pulaski **State:** TN **Zip:** 38478
Key Contact: Kim Bracey **Email:** kbracey@avkare.com
Phone Number: 931-908-0028 **Fax:** 931-292-6229

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**

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

- [ ] I. Freezer – between -25 and -10 C (-13° – 14° F)
- [ ] II. Cold – between 2 and 8 C (36° – 46° F)
- [ ] III. Cool – between 8 and 15 C (46° – 59° F)
- [x] IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
- [ ] V. Avoid Excessive Heat – above 40 C (>104° F)
- [ ] VI. Other Temperature Range Requirement (write in)
- [ ] VII. No Requirement

b. Contact for temperature excursion questions:
Name:
Number:
Is this product to be shipped to customers on ice?
Is this product to be shipped to customers on dry ice?

c. Special regulations for product in certain states?
Special returns requirements for this product?

d. Store product (unit of sale) upright?
Protect product (unit of sale) from light?

e. Shelf life: **Months**
Initial shelf life at launch (if different): **Months**

ADDITIONAL PRODUCT INFORMATION

Is the Product... Direct and Drop Ship
Legend Device? No
State Control? No
ARCOS reportable? No
Co-Licensed? No
Controlled Substance? No
Schedule No.? (incl. N for non-narcotic)
Controlled Substance Code:
Hazardous Material/Cytotoxic Agent? No

Is Item... Unit Dose
If Unit Dose, is item bar coded to unit dose for hospital scanning? Yes
Is it reverse numbered? No

ORDER INFORMATION

Unit of Sale

- [ ] Bottle
- [x] Box/Carton
- [ ] Ampule
- [ ] Glass
- [ ] Tube
- [ ] Vial Liquid Sgl
- [ ] Vial Liquid Multi
- [ ] Vial Powder Sql
- [ ] Vial Power Multi
- [ ] Other: Write In

What is the NDC selling unit?
50 pills per box
10 boxes per case
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

	Each
	Inner/Carton/Pack
1	Case

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width:	Volume (Cube)	# Pieces:
Item:	0.5	2.00"	4.25"	3.25"		1
Box/ Carton:						
Case:	5	9.50"	4.50"	6.50"		10
Pallet:						
UPC:	**Case:**					
	Carton:					

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

- [ ] Each
- [ ] Gram
- [ ] Milliliter

Other Product Information

Size/Strength/Form: 50ct/20mg/Tablet
Product Shape: round
Product Color: green
Product Imprint: Par;022

COST INFORMATION

Regular Cost Per Unit of Sale ($)	Invoice Cost (WAC) ($)	Federal Excise Tax Per Unit of Sale
$60.08	$50.07	

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: