HDMA Standard Product Information — Pharmaceutical Products

☒ New Item ☐ Promotion/Deal ☐ Open Stock ☐ Post Launch Change

Date: 8/26/14

PRODUCT INFORMATION

Manufacturer/Broker Name: AvKARE, Inc. Number:
Product Name: Zonisamide 100mg UD 5x10 Capsule
Product ID Number:
☒ NDC 50268-0816-15 ☐ UPC/GTIN #
Description: Zonisamide 100mg UD 5x10 Capsule
Address: 615 North First Street
City, State, Zip: Pulaski TN 38478
Key Contact: Kim Bracey Fax: 931-292-6229
Phone Number: 931-292-6222 Ext: 2603
Phone Number: 931-908-0028 Ext:
Is the Product? ☒ Direct Ship Item ☒ Drop Ship Item
Is the Product a Controlled Drug? ☐ Yes ☒ No
If Yes, Schedule Number:
Is this ARCOS reportable? ☐ Yes ☒ No
Is this Product a Legend Device? ☐ Yes ☒ No
Country of Origin: USA
Harmonization Code Number for International Shipping:
Is this product a Hazardous Material or Cytotoxic Agent?
☐ Yes ☒ No If yes, provide additional information on page 2.
Attach copy of Material Safety Data Sheet (MSDS)
Attach Package Insert

SPECIAL HANDLING AND STORAGE REQUIREMENTS

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

I.	Controlled Room Temperature (68° – 77° F)	☒
II.	Room Temperature (59° – 86° F)	☐
III.	Excessive Heat (>104° F)	☐
IV.	Cool (46° – 59° F)	☐
V.	Refrigerated (36° – 46° F)	☐
VI.	Frozen (-4° – 14° F)	☐
VII.	No Requirement	☐

b. Are temperature excursions permitted/allowed for product? ☐ Yes ☒ No
If Yes, provide the temperature range and hours duration:
_____ and _____

c. Are there additional storage and shipping requirements? ☐ Yes ☒ No
If yes, please provide on page 2.

ADDITIONAL PRODUCT INFORMATION

Is there a minimum order quantity?
If yes, ☒ Case ☐ Carton ☐ Item
Number of Pieces? 1
Shelf Life: ____ Months
Whsl. Code #:
Fineline Code:
Is Item? ☒ Unit Dose ☐ Unit of Use
If Unit Dose, is item bar coded to unit dose for Hospital tracking purposes?
☐ Yes ☐ No
Will handling data change in the first:
6 months? ☐ Yes
9 months? ☐ Yes
12 months? ☐ Yes
Unknown? ☐ Yes

ITEM AND PACKING INFORMATION

Size/Strength /Form	Unit Of Sale	UPC Code	Mstr. Shpr.	Inner Case Pk	Wght. Lbs.	Cube	Case Dimensions	Item Dimensions	Pallet Dimensions	# Cases/ Pallet
5 x 10 UD 100mg Cap	☐ Bottle ☒ Box ☐ Glass jar ☐ Ampule ☐ Other	Case:	500	10 box per case 5 cards per box	Case: 5.0		Depth: 9.50"	Depth: 2.00"	Depth:	
		Carton:			Carton:		Height: 4.50"	Height: 4.25"	Height:	
		Item:			Item: .50		Width: 6.50"	Width: 3.25"	Width:	

For Generic Drug Products:
I. Orange Book Rating: AB
II. Product Color: see page 2
III. Brand Name Equivalent: Zonegran®
IV. Generic Name For Brand: Zonisamide

COST INFORMATION

	Regular Cost ($)	Purchase Allowance ☐ OI ☐ BB $	Purchase Allowance %	Distribution Allowance ☐ OI ☐ BB $	Distribution Allowance %	Invoice Cost ($)	Net Cost ($)	Mfr's AWP	Avg Retl Price ($)	SRP ($)	Excise Tax
DZ											
EA						$32.33		$85.99			
PPK											

This offer is made on a proportionally equal basis to all sellers' accounts completive with customer. Signature: _____

Item Description: Zonisamide 100mg UD 5x10 Capsule **Manufacturer:** AvKARE, Inc.

If additional information is necessary, provide on right of page or as attachment.

HAZARDOUS MATERIAL INFORMATION

Is this product:

a) Cytotoxic?	☐ Yes	☒ No
b) Carcinogen?	☐ Yes	☒ No
c) Inhalation Hazard?	☐ Yes	☒ No
d) Contact Hazard?	☐ Yes	☒ No

Is this item considered a carcinogen?	☐ Yes	☒ No
Is this item an aerosol requiring special storage?	☐ Yes	☒ No
Does this product require special clean-up instructions?	☐ Yes	☒ No

If yes, attach MSDS with special instructions.

Department of Transportation (DOT) I.D. Number: _____

Hazard Class/ORM Code: _____

OSHA/DOT CHEMICAL STORAGE CLASS

Please check appropriate Class(s) for this product.

☐ ORGANIC	☐ ANTINEOPLASTIC
☐ INORGANIC	☐ STEROID/ANDROGEN
☐ CORROSIVE/OXIDIZER	☐ ESSENTIAL CHEMICAL
☐ AEROSOL	☐ PRECURSOR CHEMICAL (Describe below)
☐ AEROSOL CLASS	☐ MAXIMUM QTY LEVEL

Is the product restricted for air shipping?

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Precursor Chemical:			Size/Strength
Ephedrine	☐ Yes	☒ No	_____
Pseudoephedrine	☐ Yes	☒ No	_____
Phenylpropanolamine	☐ Yes	☒ No	_____

ADDITIONAL STORAGE AND SHIPPING REQUIREMENTS

Is this product to be shipped to customers on ice?	☐ Yes	☒ No
Is this product to be shipped to customers on dry ice?	☐ Yes	☒ No
Does this product require refrigerated truck for transport?	☐ Yes	☒ No
Is this Product State Regulated?	☐ Yes	☒ No

If yes, list states on the right or as an attachment.

Are there special returns requirements?	☐ Yes	☒ No

If yes, provide requirements in the space to the right or as attachment.

ADDITIONAL INFORMATION AS NECESSARY

Size "1" Brown Opaque Cap and White Opaque Body imprinted with 100 mg on the cap and IG228 on the body in black ink.