HDMA Standard Product Information — Pharmaceutical Products

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

Date: 11/26/14

PRODUCT INFORMATION

Manufacturer/Broker Name: AvKARE, Inc. Number: _____

Product Name: Mexiletine HCl 150 mg Capsule

Product ID Number: _____

☒ NDC 42291-0624-01 ☐ UPC/GTIN # _____

Description: Mexiletine HCl 150 mg Capsule

Address: 615 North First Street

City, State, Zip: Pulaski TN 38478

Key Contact: Debbi Shaw Fax: 931-292-6229

Phone Number: 931-292-6222 Ext: 2110

Phone Number: 931-908-2194 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? _____

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
100 Count 150 mg Capsule	☒ Bottle ☐ Box ☐ Glass jar ☐ Ampule ☐ Other _____	Case:	72		Case: 8.556 lb		Depth: 17.00"	Depth: 1.50"	Depth:	50
		Carton:			Carton:		Height: 8.00"	Height: 4.50"	Height:	
		Item:			Item: 53.9 gr		Width: 9.00"	Width: 2.25"	Width:	

For Generic Drug Products:

I. Orange Book Rating: AB

II. Product Color: See page 2

III. Brand Name Equivalent: Mexitil® Capsule

IV. Generic Name For Brand: Mexiletine HCl

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							$146.53		$253.46			
PPK												

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

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Item Description: Mexiletine HCl 150 mg 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

White granular powder in a hard gelatin capsule with an opaque tan cap and an opaque orange body, imprinted with "N" on one side and "739 and 150" on the other side in black ink

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