

PRODUCT INFORMATION

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

Product Name: Diclofenac Sodium & Misoprostol Delayed-Release Tablet

Product ID Number: _____

☒ NDC 42291-0233-60 ☐ UPC/GTIN # _____

Description: Diclofenac Sodium & Misoprostol Delayed-Release 75 mg/0.2 mg Tablet

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
60 count 75mg/0.2 mg Tablet	<input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box <input type="checkbox"/> Glass jar <input type="checkbox"/> Ampule <input type="checkbox"/> Other	Case: Carton: Item:	72		Case: 9 lb Carton: Item: 55.8g		Depth: 20.25 Height: 9.25" Width: 10.00"	Depth: Height: 4.50" Width: 2.20"	Depth: Height: Width:	36

For Generic Drug Products: I. Orange Book Rating: AB II. Product Color: See page 2

III. Brand Name Equivalent: Arthrotec® IV. Generic Name For Brand: Diclofenac w/Miso.

COST INFORMATION

Regular Cost (\$)	Purchase Allowance <input type="checkbox"/> OI <input type="checkbox"/> BB	Distribution Allowance <input type="checkbox"/> OI <input type="checkbox"/> BB	Invoice Cost (\$)	Net Cost (\$)	Mfr's AWP	Avg Retl Price (\$)	SRP (\$)	Excise Tax
DZ	\$	%	\$	%				
EA					\$160.94	\$216.40		
PPK								

This offer is made on a proportionally equal basis to all sellers' accounts complete with customer.

Signature: _____



Item Description: Diclofenac Sodium & Misoprostol Delayed-Release Tablet 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 to off-white, round, biconvex tablet, plain on one side and debossed with "0398" on the other side