



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☒ Final Version

Date: 10/3/16

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: 201089		☐ I. Freezer – between -25 and -10 C (-13° – 14° F)	
Rx Product/Proprietary Name: Diclofenac Sodium and Misoprostol Delayed-Release 50mg/.02mg Tablets 60ct		☐ II. Cold – between 2 and 8 C (36° – 46° F)	
NDC: 42291-0232-60 UPC:		☐ III. Cool – between 8 and 15 C (46° – 59° F)	
CVX Code: MXV Code:		☒ IV. Controlled Room – between 20 and 25 C (68° – 77° F)	
Description: Diclofenac Sodium and Misoprostol Delayed-Release 50mg/.02mg Tablets 60ct		allows for excursions between 15 and 30 C (59° – 86° F)	
Active ingredients:		☐ V. Avoid Excessive Heat – above 40 C (>104° F)	
URL for Additional Product Information:		☐ VI. Other Temperature Range Requirement	
Address: 615 North First Street State: TN Zip: 38478		☐ VII. No Requirement	
City: Pulaski Email: rwallace@avkare.com		b. Contact for temperature excursion questions:	
Key Contact: Rosie Wallace Fax: 931-292-6229		Name:	
Phone Number: 931-908-2195		Number:	
FOR GENERIC DRUG PRODUCTS		Is this product to be shipped to customers on ice? ☐	
I. Orange Book Rating: AB II. Brand Name: Arthrotec®		Is this product to be shipped to customers on dry ice? ☐	
III. Generic Equivalent for Brand: Diclofenac Sodium and Misoprostol		c. Special regulations for product in certain states?	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION		Special returns requirements for this product? ☐	
Does supplier meet DSCSA definition of manufacturer? Yes DUNS: 796560394		d. Store product (unit of sale) upright?	
Is product exempt from DSCSA? No		Protect product (unit of sale) from light? ☐	
If yes, select exemption:		e. Shelf life: ☐ Months	
Other exemption - Write in:		Initial shelf life at launch (if different): ☐ Months	
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			
ADDITIONAL PRODUCT INFORMATION		ITEM AND PACKING INFORMATION	
Is the Product... Direct and Drop Ship ☐ No		Weight Lbs. Dimensions (US msmts.) Volume # Pieces:	
Legend Device? ☐ No		Depth Height Width: (Cube)	
State Control? ☐ No		Item: 55.67g 3.645" 4.50" 2.25" 1	
ARCOS reportable? ☐ No		Box/ Carton:	
Co-Licensed? ☐ No		Case: 9 17.25" 7.75" 8.25" 72	
Controlled Substance? ☐ No		Pallet:	
Schedule No.? ☐ No		UPC: Case: Carton:	
(incl. N for non-narcotic)			
Controlled Substance Code: ☐ No			
Hazardous Material/Cytotoxic Agent? ☐ No			
Is Item...			
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
Is it reverse numbered?			
WHOLESALE USE ONLY:		COST INFORMATION	
Vendor #:		Regular Cost Per Unit of Sale (\$) Invoice Cost (WAC) (\$) Federal Excise Tax Per Unit of Sale	
Whsl. Code #:		As of date: 10/3/16	
Fineline Code:			
Rx billing unit to pharmacy:			
☐ Each			
☐ Gram			
☐ Milliliter			
PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer?		Size/Strength/Form:	
☐ (Write-in, e.g. 1 Vial)		60ct/50mg/.02mg/tablet	
		Product Shape: round	
		Product Color: White (white to off-white)	
		Product Imprint: 0397	

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: