

© August 2014

Introduction Type: ☐ New Item☒ Final Version

Date: 10/18/17

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																																																																															
<b>Company Name:</b> Avkare, Inc. <b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> _____ <b>DUNS:</b> 79560394 <b>Proprietary Name (if Applicable) and Established Name:</b> Acitretin 17.5mg Capsule 30ct <b>Selling Unit NDC:</b> 42291-0087-30 <b>UDI</b> _____ <b>Description:</b> Acitretin 17.5mg Capsule 30ct <b>Active Ingredient(s):</b> _____ <b>URL for Additional Product Information:</b> _____ <b>Address:</b> 815 North First Street <b>City:</b> Tussock <b>Key Contact:</b> Kim Bracey <b>Phone Number:</b> 931-908-0028 <b>Product Therapeutic Classification:</b> _____ <b>Address 2:</b> _____ <b>State:</b> TN <b>Zip:</b> 38478 <b>Email:</b> kbracey@avkare.com <b>Fax:</b> 931-292-6229				<b>a. Temperature</b> - Indicate the USP temperature range for this product. Temperature Range: _____ Other Temperature Range Requirement (write in): _____ Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No <b>b. Contact for temperature excursion questions:</b> <b>Name:</b> _____ <b>Number:</b> _____ <b>Group E-mail:</b> _____ <b>c. Special regulations for product in any states?</b> <input type="checkbox"/> No Special returns requirements for this product? _____ <b>d. Store product (unit of sale) upright?</b> <input type="checkbox"/> No Protect product (unit of sale) from light? _____ <b>e. Shelf life:</b> _____ Initial shelf life at launch (if different): _____ Months																																																																																																															
<b>ADDITIONAL PRODUCT INFORMATION</b> Is the Product... a legend device? <input type="checkbox"/> No reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No Is the Product... <input type="checkbox"/> Direct And Drop-Ship If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No If Unit Dose NDC, indicate NDC here: _____ Country of Origin <input type="checkbox"/> USA Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes				<b>PRODUCT DESCRIPTION INFORMATION</b> <b>Size:</b> 30ct <b>Strength:</b> 17.5mg <b>Dosage Form:</b> capsule <b>Product Shape:</b> capsule <b>Product Color:</b> orange <b>Product Imprint:</b> 81																																																																																																															
<b>FOR GENERIC DRUG PRODUCTS</b> I. Orange Book Rating: <input type="checkbox"/> AB <input type="checkbox"/> Authorized Generic <input type="checkbox"/> If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: Soriatane®				<b>PHARMACY ORDER / BILL UNIT</b> <b>Rec. sell unit to customer?</b> _____ (Write-in, e.g. 1 Vial) <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																																																																																																															
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b> Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> No <input type="checkbox"/> GLN: _____ Is product exempt from DSCSA? <input type="checkbox"/> No If yes, select exemption: _____ Other exemption - Write in: _____ Is product repackaged? <input type="checkbox"/> No <input type="checkbox"/> Yes Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No <input type="checkbox"/> Yes Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, was original product purchased direct from mfr? _____ If Yes, attach documentation from FDA.				<b>ITEM AND PACKING INFORMATION</b> <table border="1" style="width:100%"><thead><tr><th rowspan="2">Item:</th><th rowspan="2">Weight Lbs.</th><th colspan="3">Dimensions (US mmts.)</th><th rowspan="2">Volume (Gals)</th><th rowspan="2"># Pieces:</th></tr><tr><th>Depth</th><th>Height</th><th>Width</th></tr></thead><tbody><tr><td>Box/ Carton/ Bundle/ Inner Pack:</td><td>0.078</td><td>1.496</td><td>3.543</td><td>1.496</td><td>6.224</td><td>1</td></tr><tr><td>Case:</td><td>0.5</td><td>7.2</td><td>4.5</td><td>4.5</td><td>145.8</td><td>3</td></tr><tr><td>Pallet:</td><td></td><td></td><td></td><td></td><td>0</td><td></td></tr><tr><td>UPC:</td><td></td><td></td><td></td><td></td><td></td><td></td></tr></tbody></table>				Item:	Weight Lbs.	Dimensions (US mmts.)			Volume (Gals)	# Pieces:	Depth	Height	Width	Box/ Carton/ Bundle/ Inner Pack:	0.078	1.496	3.543	1.496	6.224	1	Case:	0.5	7.2	4.5	4.5	145.8	3	Pallet:					0		UPC:																																																																												
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<b>WHOLESALE USE ONLY:</b> Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. See new p. 3 for Designated Drop Ship Only. Signature: _____																																																																																																																			

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? ☐ No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? ☐ No

Is the product a CA Prop 65 carcinogen? ☐ No

Is the product a CA Prop 65 reproductive toxicant? ☐ No

Does the product label bear a CA Prop 65 warning? ☐ No

c. Contact Hazard? ☐ No

d. Does this product require special clean-up instructions? ☐ No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? ☐ No

Is this product regulated for shipment by DOT or IATA? ☐ No

(If yes, answer a-e below and provide SDS)

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard? ☐ No

Is the product restricted for air shipment? If so, indicate restriction:

☐ Passenger

☐ Cargo

☐ Passenger & Cargo

Is this a reportable quantity? ☐ NoRQ Threshold: Is this a marine pollutant? ☐ No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

☐ No (if yes, identify method below)

☐ Limited Quantity

☐ Consumer Commodity, ORM-D

☐ Small Quantity (49 CFR 173.4)

☐ Special Permit; DOT-SP

☐ Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

## ADD'L STORAGE INFORMATION

Is the Product... ☐ No

Controlled Substance? ☐ No

Controlled by State(s)? ☐ No

ARCOS Reportable? ☐ No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) ☐ No

If yes, indicate which:

Is it a scheduled listed chemical product? ☐ No

## CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments: 

## SDS Hazard Classification

☐ Organic ☐ Corrosive

☐ Inorganic ☐ Oxidizer

☐ Steroid/Androgen ☐ Contact Hazard

☐ Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? ☐ NoIf yes, indicate which: 

## Hazardous Waste Identification

EPA Hazardous Waste Code: 

## REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? ☐ NoIf Yes, is it managed with a pharmacy registry? Website URL: Comments / Details: (For example, iPledge program?) 

## REMS:

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments 

## Registry:

Registry Program Contact Name:  Phone: Comments 

## RETURN INSTRUCTIONS

Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? 

## MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product		Standard Order Receipt and Processing	
<b>Purchase orders may be accepted by:</b> a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #:		<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:	
Fax Number: Fax Number: Phone No.: Site Address:		Hours Days	
Name: Phone:			
<b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b> Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:		<b>Overnight and Priority Overnight PO Processing</b> <b>Overnight receipt available:</b> PO Receipt cut off time: Days of week overnight is available: <b>Priority Overnight receipt available:</b> PO Receipt Cut off time: <b>Saturday Overnight receipt available:</b> PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:	
<b>Class of Trade Restriction:</b> No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:		Monday Tuesday Wednesday Thursday Friday	
<b>Other Data Information Required to Process PO:</b> Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		<b>Return Instructions</b> Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments:	
<b>Miscellaneous Notes:</b>		<b>ADDITIONAL INFORMATION</b> Is product order for scheduled patient procedure? Is product order for restocking purposes?	