

© August 2014

Introduction Type: ☐ New Item☒ Final Version

Date: 10/18/17

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																																											
Company Name: Avkare, Inc. Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): _____ DUNS: 79560394 Proprietary Name (if Applicable) and Established Name: Acitretin 25mg Capsule 30ct Selling Unit NDC: 42291-0088-30 UDI: _____ Description: Acitretin 25mg Capsule 30ct Active Ingredient(s): _____ URL for Additional Product Information: _____ Address: 815 North First Street City: Puucki Key Contact: Kim Bracey Phone Number: 931-908-0028 Product Therapeutic Classification: _____ Address 2: _____ State: TN Zip: 38478 Email: kbracey@avkare.com Fax: 931-292-6229		a. Temperature – 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? ☐ No Is this product to be shipped to customers on dry ice? ☐ No b. Contact for temperature excursion questions: Name: _____ Number: _____ Group E-mail: _____ c. Special regulations for product in any states? ☐ No Special returns requirements for this product? _____ d. Store product (unit of sale) upright? ☐ No Protect product (unit of sale) from light? _____ e. Shelf life: _____ Initial shelf life at launch (if different): _____ Months																																																																											
ADDITIONAL PRODUCT INFORMATION Is the Product... a legend device? ☐ No reverse numbered? ☐ No co-licensed? ☐ No Is the Product... ☐ Direct And Drop-Ship If Unit Dose, is item bar coded to unit dose for hospital scanning? ☐ No If Unit Dose NDC, indicate NDC here: _____ Country of Origin: USA Is this product covered under the Trade Agreements Act (TAA)? ☐ Yes		PRODUCT DESCRIPTION INFORMATION Size: 30ct Strength: 25mg Dosage Form: capsule Product Shape: capsule Product Color: yellow Product Imprint: 83																																																																											
FOR GENERIC DRUG PRODUCTS I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Soriatane® ☐ Authorized Generic *If Authorized Generic, other section fields are not applicable		ORDER INFORMATION Unit of Sale ☒ Bottle ☐ Box/Carton ☐ Ampule ☐ Glass ☐ Tube ☐ Vial Liquid Sgl ☐ Vial Liquid Multi ☐ Vial Powder Sgl ☐ Vial Powder Multi ☐ Other: Write In _____ What is the NDC selling unit? 1 Bottle of 30 capsules (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? _____ If Yes, how many of which package type? Each _____ Inner/Carton/Pack _____ Case _____																																																																											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Does supplier meet DSCSA definition of manufacturer? ☐ No Is product exempt from DSCSA? ☐ No If yes, select exemption: _____ Other exemption - Write in: _____ Is product repackaged? ☐ No Is product sold by manufacturer's exclusive distributor? ☐ Yes Has FDA granted waiver/exception/exemption for product? ☐ No If Yes, was original product purchased direct from mfr? _____ If yes, attach documentation from FDA.		PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? _____ (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: Each _____ Gram _____ Milliliter _____																																																																											
GTIN PRODUCT INFORMATION Serialized? ☐ No If not, when? _____ Items aggregated? ☐ No <table border="1"><thead><tr><th>Level</th><th>Unit</th><th>Quantity</th><th>GTIN-14</th></tr></thead><tbody><tr><td>Item</td><td>20</td><td>Linear</td><td></td></tr><tr><td>Box/Carton/Bundle/Inner Pack</td><td>20</td><td>Linear</td><td></td></tr><tr><td>Case</td><td>20</td><td>Linear</td><td></td></tr><tr><td>Pallet</td><td>20</td><td>Linear</td><td></td></tr><tr><td></td><td>20</td><td>Linear</td><td></td></tr><tr><td></td><td>20</td><td>Linear</td><td></td></tr><tr><td></td><td>20</td><td>Linear</td><td></td></tr><tr><td></td><td>20</td><td>Linear</td><td></td></tr></tbody></table>		Level	Unit	Quantity	GTIN-14	Item	20	Linear		Box/Carton/Bundle/Inner Pack	20	Linear		Case	20	Linear		Pallet	20	Linear			20	Linear			20	Linear			20	Linear			20	Linear		ITEM AND PACKING INFORMATION <table border="1"><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>0.083</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>0.748</td><td>7.2</td><td>4.5</td><td>4.5</td><td>145.8</td><td>6</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:	0.083	1.496	3.543	1.496	6.224	1	Case:	0.748	7.2	4.5	4.5	145.8	6	Pallet:					0		UPC:						
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COST INFORMATION Regular Cost \$1,153.78 Invoice Cost (WAC) (\$) \$186.65 Federal Excise Tax Per Unit of Sale As of date: 10/18/17		WHOLESALE USE ONLY: Vendor #: _____ Whsl. Code #: _____ Fineline Code: _____																																																																											
*Please provide any additional information on page 2. 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	
Purchase orders may be accepted by: 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 #:		Purchase order daily receipt cut off time by supplier 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:			
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:		Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:	
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:		Phone #: Fax #:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Return Instructions 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:	
Miscellaneous Notes:		ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?	