



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date: 2/24/16

| | |
|--------------------------------------------------|-------------------------------|
| PRODUCT INFORMATION | |
| Company Name: | AvKARE, INC |
| Application Number for NDA/ANDA/BLA, Med Device: | OTC |
| Rx Product/Proprietary Name: | Vitamin D3 5000IU 50ct Tablet |
| NDC: | 50268-0866-15 |
| CVX Code: | |
| UPC: | |
| MXV Code: | |
| Description: | Vitamin D3 5000IU 50ct Tablet |
| Active Ingredients: | |
| URL for Additional Product Information: | |
| Address: | 615 North First Street |
| City: | Pulaski |
| State: | TN |
| Zip: | 38478 |
| Key Contact: | Kim Bracey |
| Phone Number: | 931-908-0028 |
| Email: | kbracey@avkare.com |
| Fax: | 931-292-6229 |

| | |
|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| SPECIAL HANDLING AND STORAGE REQUIREMENTS* | |
| a. Temperature – Indicate the USP temperature range for this product. | |
| <input type="checkbox"/> | I. Freezer – between -25 and -10 C (-13° – 14° F) |
| <input type="checkbox"/> | II. Cold – between 2 and 8 C (36° – 46° F) |
| <input type="checkbox"/> | III. Cool – between 8 and 15 C (46° – 59° F) |
| <input checked="" type="checkbox"/> | IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) |
| <input type="checkbox"/> | V. Avoid Excessive Heat – above 40 C (>104° F) |
| <input type="checkbox"/> | VI. Other Temperature Range Requirement (write in) _____ |
| <input type="checkbox"/> | VII. No Requirement |
| b. Contact for temperature excursion questions: | |
| Name: | _____ |
| Number: | _____ |
| Is this product to be shipped to customers on ice? _____ | |
| Is this product to be shipped to customers on dry ice? _____ | |

| | |
|-----------------------------------------------------------|--------------------|
| FOR GENERIC DRUG PRODUCTS | |
| I. Orange Book Rating: | _____ |
| II. Brand Name: | _____ |
| III. Generic Equivalent for Brand: | _____ |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
| Does supplier meet DSCSA definition of manufacturer? | Yes _____ No _____ |
| DUNS: | 796580394 |
| Is product exempt from DSCSA? | No _____ |
| If yes, select exemption: | _____ |
| Other exemption - Write in: | _____ |
| Is product repackaged? | Yes _____ No _____ |
| If Yes, was original product purchased direct from mfr? | Yes _____ No _____ |
| Is product sold by manufacturer's exclusive distributor? | Yes _____ No _____ |
| Are any waivers granted for product ID/barcode? | Yes _____ No _____ |
| If yes, attach documentation from FDA | _____ |

| | |
|--------------------------------------------------------------|--------------|
| c. Special regulations for product in certain states? | |
| Special returns requirements for this product? | _____ |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | _____ |
| e. Shelf life: _____ Months | |
| Initial shelf life at launch (if different): | _____ Months |

| | |
|---------------------------------------------------------------------|--------------------|
| ADDITIONAL PRODUCT INFORMATION | |
| Is the Product... Direct and Drop Ship | _____ |
| Legend Device? | No _____ |
| State Control? | No _____ |
| ARCOS reportable? | No _____ |
| Co-Licensed? | No _____ |
| Controlled Substance? | No _____ |
| Schedule No.? | _____ |
| (incl. N for non-narcotic) | _____ |
| Controlled Substance Code: | _____ |
| Hazardous Material/Cytotoxic Agent? | No _____ |
| Is Item... Unit Dose | _____ |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | Yes _____ No _____ |
| Is it reverse numbered? | No _____ |

| | | | | | | |
|-------------------------------------|------------------------|--------|-----------|-------|--|----|
| ITEM AND PACKING INFORMATION | | | | | | |
| Weight Lbs. | Dimensions (US msmts.) | Volume | # Pieces: | | | |
| Depth | Height | Width | | | | |
| Item: | 0.5 | 2.00" | 4.25" | 3.25" | | 1 |
| Box/ Carton: | | | | | | |
| Case: | 5 | 9.50" | 4.50" | 6.50" | | 10 |
| Pallet: | | | | | | |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| | |
|-----------------------------------|-------|
| PHARMACY ORDER / BILL UNIT | |
| Rec. sell unit to customer? | _____ |
| (Write-in, e.g. 1 Vial) | _____ |
| Rx billing unit to pharmacy: | _____ |
| Each | _____ |
| Gram | _____ |
| Milliliter | _____ |

| | | |
|------------------------------------|-------------------------|-------------------------------------|
| Other Product Information | | |
| Size/Strength/Form: | 50ct/5000IU/ Tablet | |
| Product Shape: | Round | |
| Product Color: | White | |
| Product Imprint: | _____ | |
| COST INFORMATION | | |
| Regular Cost Per Unit of Sale (\$) | Invoice Cost (WAC) (\$) | Federal Excise Tax Per Unit of Sale |
| \$16.23 | \$13.53 | |
| As of date: 2/24/16 | | |

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: _____