



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date: 3/31/16

PRODUCT INFORMATION				
Company Name:	AvKARE, INC		Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	OTC			
Rx Product/Proprietary Name:	Vitamin D3 400IU 50cct Tablet			
NDC:	50268-0863-15	UPC:		
CVX Code:		MXV Code:		
Description:	Vitamin D3 400IU 50cct Tablet			
Active Ingredients:				
URL for Additional Product Information:				
Address:	615 North First Street	Address 2:		
City:	Pulaski	State:	TN	
Key Contact:	Kim Bracey	Email:	kbracey@avkare.com	
Phone Number:	931-908-0028	Fax:	931-292-6229	
Zip:	38478			

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 _____ DUNS: 796580394
Is product exempt from DSCSA?	No _____
If yes, select exemption:	_____
Other exemption - Write in:	_____
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

ITEM AND PACKING INFORMATION	
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.?	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 _____
Is it reverse numbered?	No _____

ORDER INFORMATION	
What is the NDC selling unit?	50 pills per box
	10 boxes per case
	(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity?	Yes _____
If Yes, how many of which package type?	
	Each _____
	Inner/Outer/Pack _____
	Case _____

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

COST INFORMATION	
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)
\$14.04	\$11.70
Federal Excise Tax Per Unit of Sale	

As of date: 3/31/16	

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: _____



Standard Pharmaceutical Product Information (Page 2)

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
- ☐ Carcinogen
- ☐ Reproductive Toxicant
- ☐ Both
- ☐ Warning appears on label
- 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

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT? ☐ No

(if yes, answer a-d below and provide SDS)

Is this a reportable quantity? ☐ No

a. DOT Hazard Class

RQ Threshold:

b. UN/ID Number

Is this a marine pollutant? ☐ No

c. Packing Group

Is this product shipped utilizing an authorized DOT exception or Special Permit? ☐ No

d. Inhalation Hazard?

(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#

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

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

- ☐ Organic ☐ Inorganic
- ☐ Antineoplastic ☐ Steroid/Androgen
- ☐ Corrosive ☐ Oxidizer
- ☐ Aerosol Class; Identify NFPA Storage Level:

☐ Listed Chemical (List I or II) (Indicate or Write-in below):

- ☐ Ephedrine
- ☐ Pseudoephedrine
- ☐ Phenylpropanolamine
- ☐ Iodine ($\geq 2.2\%$)
- ☐ Other:

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:

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	Level	How?	GTIN-14
Item	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID
Box/Case	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID
Case	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID
Pallet	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

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?

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

50268-0865-15

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



Standard Pharmaceutical Product Information (Page 3)

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