# HDMA Standard Product Information — Pharmaceutical Products

☒ New Item ☐ Promotion/Deal ☐ Open Stock ☐ Post Launch Change

Date: 09/25/2014 

## PRODUCT INFORMATION

Manufacturer/Broker Name: AvKARE, Inc. Number:
Product Name: Hydrocodone Bitartrate/Acetaminophen Tablets
Product ID Number:
☒ NDC 50268-0402-15 ☐ UPC/GTIN #
Description: Hydrocodone Bitartrate/Acetaminophen Tablets 10mg/325mg UD50
Address: 615 North First Street
City, State, Zip: Pulaski TN 38478
Key Contact: Kim Bracey Fax: 931-292-6229
Phone Number: 931-292-6222 Ext: 2603
Phone Number: 931-908-0028 Ext:
Is the Product? ☒ Direct Ship Item ☒ Drop Ship Item
Is the Product a Controlled Drug? ☒ Yes ☐ No
If Yes, Schedule Number: CII
Is this ARCOS reportable? ☒ Yes ☐ No
Is this Product a Legend Device? ☐ Yes ☒ No
Country of Origin: USA
Harmonization Code Number for International Shipping:
Is this product a Hazardous Material or Cytotoxic Agent?
☐ Yes ☒ No If yes, provide additional information on page 2.
Attach copy of Material Safety Data Sheet (MSDS)
Attach Package Insert

## SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature – Indicate the normal temperature range for this product.

| | | |
|---|---|---|
| I. | Controlled Room Temperature (68° – 77° F) | ☒ |
| II. | Room Temperature (59° – 86° F) | ☐ |
| III. | Excessive Heat (>104° F) | ☐ |
| IV. | Cool (46° – 59° F) | ☐ |
| V. | Refrigerated (36° – 46° F) | ☐ |
| VI. | Frozen (-4° – 14° F) | ☐ |
| VII. | No Requirement | ☐ |

b. Are temperature excursions permitted/allowed for product? ☐ Yes ☒ No
If Yes, provide the temperature range and hours duration:
_____ and _____

c. Are there additional storage and shipping requirements? ☐ Yes ☒ No
If yes, please provide on page 2.

## ADDITIONAL PRODUCT INFORMATION

Is there a minimum order quantity?
If yes, ☒ Case ☐ Carton ☐ Item
Number of Pieces? 1
Shelf Life: ____ Months
Whsl. Code #:
Fineline Code:
Is Item? ☒ Unit Dose ☐ Unit of Use
If Unit Dose, is item bar coded to unit dose for Hospital tracking purposes?
☐ Yes ☐ No
Will handling data change in the first:
6 months? ☐ Yes
9 months? ☐ Yes
12 months? ☐ Yes
Unknown? ☐ Yes

## ITEM AND PACKING INFORMATION

| Size/Strength /Form | Unit Of Sale | UPC Code | Mstr. Shpr. | Inner Case Pk | Wght. Lbs. | Cube | Case Dimensions | Item Dimensions | Pallet Dimensions | # Cases/ Pallet |
|---|---|---|---|---|---|---|---|---|---|---|
| 5 x 10 10mg/325mg Tablet | ☐ Bottle ☒ Box ☐ Glass jar ☐ Ampule ☐ Other | Case: | | 10 Box per case | Case: 5.0 | | Depth: 9.50" | Depth: 2.00" | Depth: | |
| | | Carton: | | | Carton: | | Height: 4.50" | Height: 4.25" | Height: | |
| | | Item: | | | Item: .50 | | Width: 6.50" | Width: 3.25" | Width: | |

For Generic Drug Products:
I. Orange Book Rating: AA
II. Product Color: See Page 2
III. Brand Name Equivalent: Norco™
IV. Generic Name For Brand: Hydrocodone/APAP

## COST INFORMATION

| | Regular Cost ($) | | Purchase Allowance ☐ OI ☐ BB $ | Purchase Allowance % | Distribution Allowance ☐ OI ☐ BB $ | Distribution Allowance % | Invoice Cost ($) | Net Cost ($) | Mfr's AWP | Avg Retl Price ($) | SRP ($) | Excise Tax |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DZ | | | | | | | | | | | | |
| EA | | | | | | | $31.94 | | $78.27 | | | |
| PPK | | | | | | | | | | | | |

This offer is made on a proportionally equal basis to all sellers' accounts completive with customer. Signature: _____

**Item Description:** Hydrocodone Bitartrate/Acetaminophen Tablets, USP **Manufacturer:** AvKARE, Inc.

*If additional information is necessary, provide on right of page or as attachment.*

## HAZARDOUS MATERIAL INFORMATION

Is this product:

- a) Cytotoxic? ☐ Yes ☒ No
- b) Carcinogen? ☐ Yes ☒ No
- c) Inhalation Hazard? ☐ Yes ☒ No
- d) Contact Hazard? ☐ Yes ☒ No

Is this item considered a carcinogen? ☐ Yes ☒ No

Is this item an aerosol requiring special storage? ☐ Yes ☒ No

Does this product require special clean-up instructions? ☐ Yes ☒ No

If yes, attach MSDS with special instructions.

Department of Transportation (DOT) I.D. Number: _____

Hazard Class/ORM Code: _____

## OSHA/DOT CHEMICAL STORAGE CLASS

Please check appropriate Class(s) for this product.

| | |
|---|---|
| ☐ ORGANIC | ☐ ANTINEOPLASTIC |
| ☐ INORGANIC | ☐ STEROID/ANDROGEN |
| ☐ CORROSIVE/OXIDIZER | ☐ ESSENTIAL CHEMICAL |
| ☐ AEROSOL | ☐ PRECURSOR CHEMICAL (Describe below) |
| ☐ AEROSOL CLASS | ☐ MAXIMUM QTY LEVEL |

Is the product restricted for air shipping?

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

| Precursor Chemical: | | | Size/Strength |
|---|---|---|---|
| Ephedrine | ☐ Yes | ☒ No | _____ |
| Pseudoephedrine | ☐ Yes | ☒ No | _____ |
| Phenylpropanolamine | ☐ Yes | ☒ No | _____ |

## ADDITIONAL STORAGE AND SHIPPING REQUIREMENTS

Is this product to be shipped to customers on ice? ☐ Yes ☒ No

Is this product to be shipped to customers on dry ice? ☐ Yes ☒ No

Does this product require refrigerated truck for transport? ☐ Yes ☒ No

Is this Product State Regulated? ☐ Yes ☒ No

If yes, list states on the right or as an attachment.

Are there special returns requirements? ☐ Yes ☒ No

If yes, provide requirements in the space to the right or as attachment.

## ADDITIONAL INFORMATION AS NECESSARY

White to off-white, score, oblong biconvex tablet, debossed "IP"bisect "110" on obverse and plain on the reverse