HDA Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item | X Final Version | **Date:** 5/12/17

PRODUCT INFORMATION

Company Name: AvKARE, Inc
Application: ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 206392
DUNS: 796560394
Proprietary Name (If Applicable) and Established Name: Aspirin and ER Dipyridamole 25mg/200mg Capsuel 60ct
Selling Unit NDC: 42291-0116-60
Individual Unit NDC:
UPC:
UDI
CVX Code:
MVX Code:
Description: Aspirin and ER Dipyridamole 25mg/200mg Capsuel 60ct
Active Ingredient(s):
URL for Additional Product Information:
Address: 615 North First Street
Address 2:
City: Pulaski
State: TN
Zip: 38478
Key Contact: Kim Bracey
Email: kbracey@avkare.com
Phone Number: 931-908-0028
Fax: 931-292-6229
Product Therapeutic Classification:

ADDITIONAL PRODUCT INFORMATION

Is the Product...
a legend device? No
reverse numbered? No
co-licensed? No
Is the Product... Direct And Drop-Ship
Is the Product...

If Unit Dose, is item bar coded to unit dose for hospital scanning?
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:	60ct
Strength:	25/200mg
Dosage Form:	Capsule
Product Shape:	capsule
Product Color:	red, yellow
Product Imprint:	AN;596

FOR GENERIC DRUG PRODUCTS

Authorized Generic

*If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB
II. Generic Equivalent to What Brand?: Aggrenox

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? No
GLN:
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.

GTIN PRODUCT INFORMATION

Level	Saleable Unit	2D	Linear	Quantity	GTIN-14
Item		2D	Linear		
Box/Carton/Bundle/Inner Pack		2D	Linear		
Case		2D	Linear		
Pallet		2D	Linear		
		2D	Linear		
		2D	Linear		
		2D	Linear		
		2D	Linear		

Serialized?
If not, when?
Items aggregated?

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)
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
Months

ORDER INFORMATION

Unit of Sale
X Bottle
Box/Carton
Ampule
Glass
Tube
Vial Liquid Sgl
Vial Liquid Multi
Vial Powder Sgl
Vial Power Multi
Other: Write In

What is the NDC selling unit? 1 Bottle of 60 Capsules
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?
Each
Inner/Carton/Pack
1 Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:
Each
Gram
Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	75.48g	4.25	4.5	2.2	42.075	1
Box/Carton/Bundle/ Inner Pack:					0	
Case:	12lbs	20.25	9.25	10	1873.125	72
Pallet:					0	
UPC:	**Case:**					
	Carton:					

COST INFORMATION

Regular Cost	$415.51
Invoice Cost (WAC) ($)	$157.16
Federal Excise Tax Per Unit of Sale	
As of date:	5/12/17

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

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: