



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date: 1/22/15

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name: AvKARE, INC		a. Temperature – Indicate the USP temperature range for this product.	
Application Number for NDA/ANDA/BLA, Med Device: 77-883		<input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F)	
Rx Product/Proprietary Name: Balsalazide Disodium 750mg Capsule		<input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F)	
NDC: 50268-0102-13		<input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F)	
CVX Code:		<input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F)	
UPC:		allows for excursions between 15 and 30 C (59° – 86° F)	
MXV Code:		<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)	
Description: Balsalazide Disodium 750mg Capsule		<input type="checkbox"/> VI. Other Temperature Range Requirement (write in)	
Active Ingredients:		<input type="checkbox"/> VII. No Requirement	
URL for Additional Product Information:		b. Contact for temperature excursion questions:	
Address: 615 North First Street		Name:	
City: Pulaski		Number:	
State: TN		Is this product to be shipped to customers on ice?	
Zip: 38478		Is this product to be shipped to customers on dry ice?	
Key Contact: Kim Bracey		c. Special regulations for product in certain states?	
Phone Number: 931-908-0028		Special returns requirements for this product?	
Email: kbracey@avkare.com		d. Store product (unit of sale) upright?	
Fax: 931-292-6229		Protect product (unit of sale) from light?	
FOR GENERIC DRUG PRODUCTS		e. Shelf life: Months	
I. Orange Book Rating: AB		Initial shelf life at launch (if different): Months	
II. Brand Name: Colazal®			
III. Generic Equivalent for Brand: Balsalazide Disodium			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION			
Does supplier meet DSCSA definition of manufacturer? No		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	
ADDITIONAL PRODUCT INFORMATION		ITEM AND PACKING INFORMATION	
Is the Product... Direct and Drop Ship		Weight Lbs.	
Legend Device? No		Dimensions (US msmts.)	
State Control? No		Depth	
ARCOS reportable? No		Height	
Co-Licensed? No		Width:	
Controlled Substance? No		Volume (Cube)	
Schedule No.? No		# Pieces:	
(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			
WHOLESALE USE ONLY:			
Vendor #:			
Whsl. Code #:			
Fineline Code:			
Unit of Sale		What is the NDC selling unit?	
<input type="checkbox"/> Bottle		30 pills per box	
<input checked="" type="checkbox"/> Box/ Carton		10 boxes per case	
<input type="checkbox"/> Ampule		(Write-in, e.g. 1 Box of 10 Vials)	
<input type="checkbox"/> Glass			
<input type="checkbox"/> Tube			
<input type="checkbox"/> Vial Liquid Sgl			
<input type="checkbox"/> Vial Liquid Multi			
<input type="checkbox"/> Vial Powder Sgl			
<input type="checkbox"/> Vial Powder Multi			
<input type="checkbox"/> Other: Write In			
Minimum order quantity? Yes			
If Yes, how many of which package type?			
<input type="checkbox"/> Each			
<input type="checkbox"/> Inner/ Carton/ Pack			
<input type="checkbox"/> Case			
PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer?		Size/Strength/Form:	
(Write-in, e.g. 1 Vial)		3x10 750mg Tablet	
Rx billing unit to pharmacy:		Product Shape: capsule shaped	
<input type="checkbox"/> Each		Product Color: white, opaque capsule	
<input type="checkbox"/> Gram		Product Imprint: imprinted "APO B750" in red ink	
<input type="checkbox"/> Milliliter			
		Regular Cost Per Unit of Sale (\$)	
		Invoice Cost (WAC) (\$)	
		Federal Excise Tax Per Unit of Sale	
		\$60.45	
		As of date: 1/22/15	

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: