© August 2014		Introduction Type: New Item					Fi	inal Version		Date:	1/2	22/15	
PRODUCT INFORMATION								SPECIAL HA	NDLING AND S	TORAGE REQU	JIREMENTS*		
Company Name: AvKARE, INC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA, Med Device: 77-883							I.	Freezer - bet	ween -25 and -	10 C (-13° - 14	° F)		
Rx Product/Proprietary Name: Balsalazide Disodium 750mg Capsule							II. Cold – between 2 and 8 C (36° – 46° F)						
NDC: 50268-0102-13 UPC:							III	I. Cool - between	en 8 and 15 C	(46° – 59° F)			
CVX Code:			MVX Code:				x IV. Controlled Room – between 20 and 25 C (68° – 77° F)						
Description:	Balsalazide Disodiur	m 750mg Capsul	e				allows for excursions between 15 and 30 C (59° – 86° F)						
-										ove 40 C (>104°	' F)		
Active ingredients:							VI. Other Temperature Range Requirement (write in)						
URL for Additional Product Information:						VII. No Requirement							
Address: 615 North First Street			Address 2:				b. Contact for temperature excursion questions:						
City:	Pulaski		State: TN		Zip: 38478		Name:						
Key Contact:	Kim Bracey		Email:	kbracey@av			Number:						
Phone Number: 931-908-0028			Fax:	931-292-6229)			ed to customer					
		FOR	R GENERIC DRUG PRODUC	CTS			Is this produc	ct to be shippe	ed to customer	s on dry ice?			
I. Orange Book Rating:	AB		II. Brand Name:	Colazal®									
III. Generic Equivalent for Brand: Balsalazide D			isodium				c. Special regu	lations for pr	oduct in certai	n states?			
	DR	UG SUPPLY CH	AIN SECURITY ACT (DSCSA) INFORMATION				Special return	ns requiremen	ts for this prod	uct?			
Does supplier meet DSC	SA definition of manu	facturer?	No DUNS : 796560394									_	
Is product exempt from DSCSA? No			<u>_</u>				d. Store product (unit of sale) upright?						
If yes, select exemption:			<u> </u>				Protect pro	duct (unit of s	ale) from light	?			
Other exemption - Wri	ite in:						-					_	
Is product repackaged? Yes			If Yes, was original product purchased direct from mfr?				e. Shelf life:		Months				
Is product sold by manuf		listributor?	Yes		-			Initial chalf	ife at launch (if different).			
Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA								IIII liai Sileii i	ne at launch (ii dillerelle,		Months	
Are any waivers granted	I for product ID/barco			If yes, attacl	n documentation from FDA			illitiai sileii i	ne at raunon (ir dinorcin,		Months	
Are any waivers granted	I for product ID/barco	de?		If yes, attacl	n documentation from FDA				PACKING INF			Months	
Is the Product	Direct and Drop Ship	de? ADDITIONAL	No	If yes, attack			Weight I be	ITEM AND	•	ORMATION	Volume		
,		ADDITIONAL No	No PRODUCT INFORMATION Unit of Sale	ORDER INFOR			Weight Lbs.	ITEM AND	PACKING INF	ORMATION	Volume (Cube)	# Pieces:	
Is the Product Legend Device? State Control?		ADDITIONAL No No	No PRODUCT INFORMATION Unit of Sale Bottle	ORDER INFOR What is the I	RMATION NDC selling unit?	Item:	Weight Lbs.	ITEM AND	PACKING INF	ORMATION			
Is the Product Legend Device? State Control? ARCOS reportable?		ADDITIONAL No No No	No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton	ORDER INFORMATION What is the II 30 pills per but 10 boxes per	RMATION NDC selling unit?			ITEM AND Dim Depth	PACKING INF nensions (US n Height	ORMATION nsmts.) Width:			
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed?		de? ADDITIONAL No No No No No	No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule	ORDER INFORMATION What is the II 30 pills per but 10 boxes per	RMATION NDC selling unit?	Box/		ITEM AND Dim Depth	PACKING INF nensions (US n Height	ORMATION nsmts.) Width:			
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?		ADDITIONAL No No No	No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass	ORDER INFORMATION What is the I 30 pills per b 10 boxes per (Write-in, e.g.	RMATION UDC selling unit? ox case J. 1 Box of 10 Vials)	Box/ Carton:	0.5	Dim Depth 2.00"	PACKING INF nensions (US n Height 4.25"	ORMATION nsmts.) Width: 3.25"			
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	Direct and Drop Ship	de? ADDITIONAL No No No No No	No PRODUCT INFORMATION Unit of Sale Bottle X Box/Carton Ampule Glass Tube	ORDER INFORMATION What is the I 30 pills per b 10 boxes per (Write-in, e.g.	RMATION NDC selling unit?	Box/		ITEM AND Dim Depth	PACKING INF nensions (US n Height	ORMATION nsmts.) Width:			
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	Direct and Drop Ship	de? ADDITIONAL No No No No No	No PRODUCT INFORMATION Unit of Sale Bottle x Box/Carton Ampule Glass	ORDER INFOR What is the I 30 pills per b 10 boxes per (Write-in, e.(RMATION UDC selling unit? ox case J. 1 Box of 10 Vials)	Box/ Carton: Case:	0.5	Dim Depth 2.00"	PACKING INF nensions (US n Height 4.25"	ORMATION nsmts.) Width: 3.25"			
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcol	Direct and Drop Ship	de? ADDITIONAL No No No No No	No Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	ORDER INFOR What is the I 30 pills per b 10 boxes per (Write-in, e.(RMATION NDC selling unit? ox case 3. 1 Box of 10 Vials) der quantity? rany of which package type? Each	Box/ Carton:	0.5	Dim Depth 2.00"	PACKING INF nensions (US n Height 4.25"	ORMATION nsmts.) Width: 3.25"			
Is the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcol Controlled Substance Co Hazardous Material/Cyto	Direct and Drop Ship Lic) de: toxic Agent?	ADDITIONAL NO NO NO NO NO NO	No Unit of Sale Bottle Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Vial Powder Sql Vial Vial Power Multi	ORDER INFOR What is the I 30 pills per b 10 boxes per (Write-in, e.(RMATION NDC selling unit? ox case j. 1 Box of 10 Vials) der quantity? Tes many of which package type? Each Inner/Carton/Pack	Box/ Carton: Case:	0.5 3	Dim Depth 2.00"	PACKING INF nensions (US n Height 4.25"	ORMATION nsmts.) Width: 3.25"			
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