



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name: AvKARE, INC. Application: ANDA		a. Temperature – Indicate the USP temperature range for this product.	
Application Number for NDA/ANDA/BLA, Med Device: 201504		<input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F)	
Rx Product/Proprietary Name: Quetiapine Fumarate 300mg Tablet UD50		<input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F)	
NDC: 50268-0634-15 UPC:		<input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F)	
CVX Code: MXV Code:		<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)	
Description: Quetiapine Fumarate 300mg Tablet UD50		<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)	
Active Ingredients:		<input type="checkbox"/> VI. Other Temperature Range Requirement (write in)	
URL for Additional Product Information:		<input type="checkbox"/> 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@avkare.com		Number:	
Phone Number: 931-908-0028 Fax: 931-292-6229		Is this product to be shipped to customers on ice? <input type="checkbox"/>	
		Is this product to be shipped to customers on dry ice? <input type="checkbox"/>	
I. Orange Book Rating: AB II. Brand Name: Seroquel		c. Special regulations for product in certain states?	
III. Generic Equivalent for Brand: Quetiapine Fumarate		Special returns requirements for this product? <input type="checkbox"/>	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION		d. Store product (unit of sale) upright?	
Does supplier meet DSCSA definition of manufacturer? Yes DUNS: 796560394		Protect product (unit of sale) from light? <input type="checkbox"/>	
Is product exempt from DSCSA? No		e. Shelf life: <input type="text"/> Months	
If yes, select exemption:		Initial shelf life at launch (if different): <input type="text"/> Months	
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. Dimensions (US msmts.) Volume # Pieces:	
Legend Device? No		Depth Height Width:	
State Control? No		Item: 0.5 2.00" 4.25" 3.25" <input type="text"/>	
ARCOS reportable? No		Box/ Carton:	
Co-Licensed? No		Case: 5 9.50" 4.50" 6.50" <input type="text"/>	
Controlled Substance? No		Pallet:	
Schedule No.? (incl. N for non-narcotic)		UPC: Case: Carton:	
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:		COST INFORMATION	
Vendor #:		Regular Cost Per Unit of Sale (\$) Invoice Cost (WAC) (\$) Federal Excise Tax Per Unit of Sale	
Whsl. Code #:		<input type="text"/> <input type="text"/> <input type="text"/>	
Fineline Code:		As of date: 6/2/16	
Unit of Sale			
<input type="checkbox"/> Bottle			
<input checked="" type="checkbox"/> Box/Carton			
<input type="checkbox"/> Ampule			
<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			
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?			
<input type="checkbox"/> Each			
<input type="checkbox"/> Inner/Carton/Pack			
<input type="checkbox"/> Case			
PHARMACY ORDER / BILL UNIT			
Rec. sell unit to customer?			
(Write-in, e.g. 1 Vial)			
Rx billing unit to pharmacy:			
<input type="checkbox"/> Each			
<input type="checkbox"/> Gram			
<input type="checkbox"/> Milliliter			
Size/Strength/Form:			
50/300mg/ Tablet			
Product Shape: round(biconvex)			
Product Color: white			
Product Imprint: 259			

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: