



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	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 25mg Tablet UD50	<input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F)	
NDC:	50268-0630-15	<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)	
Description:	Quetiapine Fumarate 25mg Tablet UD50	allows for excursions between 15 and 30 C (59° – 86° F)	
Active Ingredients:		<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)	
URL for Additional Product Information:		<input type="checkbox"/> VI. Other Temperature Range Requirement (write in) _____	
Address:	615 North First Street	<input type="checkbox"/> VII. No Requirement	
City:	Pulaski	b. Contact for temperature excursion questions:	
State:	TN	Name: _____	
Key Contact:	Kim Bracey	Number: _____	
Phone Number:	931-908-0028	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"/>	
FOR GENERIC DRUG PRODUCTS		c. Special regulations for product in certain states?	
I. Orange Book Rating:	AB	Special returns requirements for this product? <input type="checkbox"/>	
II. Brand Name:	Seroquel	d. Store product (unit of sale) upright? <input type="checkbox"/>	
III. Generic Equivalent for Brand:	Quetiapine Fumarate	Protect product (unit of sale) from light? <input type="checkbox"/>	
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION		e. Shelf life: _____ Months	
Does supplier meet DSCSA definition of manufacturer?	Yes	Initial shelf life at launch (if different): _____ Months	
DUNS:	796560394		
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		
ADDITIONAL PRODUCT INFORMATION		ITEM AND PACKING INFORMATION	
Is the Product...	Direct Ship Item	Weight Lbs. Dimensions (US msmts.) Volume # Pieces:	
Legend Device?	No	Depth Height Width: (Cube)	
State Control?	No	Item: 0.5 2.00" 4.25" 3.25" 1	
ARCOS reportable?	No	Box/ Carton: 5 9.50" 4.50" 6.50" 10	
Co-Licensed?	No	Pallet: Case: Carton:	
Controlled Substance?	No	UPC: Case: Carton:	
Schedule No.?	No		
(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:		COST INFORMATION	
Vendor #:		Regular Cost Per Unit of Sale (\$)	
Whsl. Code #:		Invoice Cost (WAC) (\$)	
Fineline Code:		Federal Excise Tax Per Unit of Sale	
		As of date: 6/2/16	
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: _____			