

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

☐ Final Version

Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																											
Company Name: AvKARE, INC Application: ANDA Application Number for NDA/ANDA/BLA, Med Device: 201504		a. Temperature – Indicate the USP temperature range for this product. ☐ I. Freezer – between -25 and -10 C (-13° – 14° F) ☐ II. Cold – between 2 and 8 C (36° – 46° F) ☐ III. Cool – between 8 and 15 C (46° – 59° F) ☒ IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) ☐ V. Avoid Excessive Heat – above 40 C (>104° F) ☐ VI. Other Temperature Range Requirement (write in) ☐ VII. No Requirement																																																											
Rx Product/Proprietary Name: Quetiapine Fumarate 200mg Tablet UD50 NDC: 50268-0633-15 UPC: CVX Code: MVX Code: 																																																													
Description: Quetiapine Fumarate 200mg Tablet UD50 Active ingredients: 																																																													
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																																																													
FOR GENERIC DRUG PRODUCTS																																																													
I. Orange Book Rating: AB II. Brand Name: Seroquel III. Generic Equivalent for Brand: Quetiapine Fumarate		b. Contact for temperature excursion questions: Name: Number: Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice? 																																																											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																																													
Does supplier meet DSCSA definition of manufacturer? Yes 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 there any waivers granted for product ID/barcode? No If yes, attach documentation from FDA 																																																													
ADDITIONAL PRODUCT INFORMATION																																																													
Is the Product... Direct and Drop Ship Legend Device? No State Control? No ARCOS reportable? No Co-Licensed? No Controlled Substance? No Schedule 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																																																													
Unit of Sale ☐ Bottle ☒ Box/ Carton ☐ Ampule ☐ Glass ☐ Tube ☐ Vial Liquid Sgl ☐ Vial Liquid Multi ☐ Vial Powder Sgl ☐ Vial Power Multi ☐ Other: Write In ORDER INFORMATION 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? ☐ Each ☐ Inner/ Carton/ Pack ☐ Case 1 		ITEM AND PACKING INFORMATION																																																											
WHOLESALE USE ONLY: Vendor #: Whsl. Code #: Finline Code: 		Weight Lbs. <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Item:</th> <th>Weight Lbs.</th> <th>Depth</th> <th>Height</th> <th>Width:</th> <th>Volume (Cube)</th> <th># Pieces:</th> </tr> </thead> <tbody> <tr> <td>Box/ Carton:</td> <td>0.5</td> <td>2.00"</td> <td>4.25"</td> <td>3.25"</td> <td></td> <td>1</td> </tr> <tr> <td>Case:</td> <td>5</td> <td>9.50"</td> <td>4.50"</td> <td>6.50"</td> <td></td> <td>10</td> </tr> <tr> <td>Pallet:</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>UPC:</td> <td>Case:</td> <td colspan="4"></td> <td></td> </tr> <tr> <td></td> <td>Carton:</td> <td colspan="4"></td> <td></td> </tr> </tbody> </table> Dimensions (US msmts.) <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Weight Lbs.</th> <th>Depth</th> <th>Height</th> <th>Width:</th> </tr> </thead> <tbody> <tr> <td>0.5</td> <td>2.00"</td> <td>4.25"</td> <td>3.25"</td> </tr> <tr> <td>5</td> <td>9.50"</td> <td>4.50"</td> <td>6.50"</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Item:	Weight Lbs.	Depth	Height	Width:	Volume (Cube)	# Pieces:	Box/ Carton:	0.5	2.00"	4.25"	3.25"		1	Case:	5	9.50"	4.50"	6.50"		10	Pallet:							UPC:	Case:							Carton:						Weight Lbs.	Depth	Height	Width:	0.5	2.00"	4.25"	3.25"	5	9.50"	4.50"	6.50"				
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PHARMACY ORDER / BILL UNIT																																																													
Rec. sell unit to customer? (Write-in, e.g. 1 Vial)		COST INFORMATION																																																											
Rx billing unit to pharmacy: ☐ Each ☐ Gram ☐ Milliliter		Regular Cost Per Unit of Sale (\$) \$608.67 Invoice Cost (WAC) (\$) \$52.80 Federal Excise Tax Per Unit of Sale 																																																											
Size/Strength/Form: 50/200mg/ Tablet Product Shape: round(biconvex) Product Color: white Product Imprint: 260		As of date: 6/2/16																																																											