



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☒ Final Version

Date: 8/10/16

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>Company Name:</b> AvKARE, Inc <b>Application:</b> ANDA		<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
<b>Application Number for NDA/ANDA/BLA, Med Device:</b> 200405		<input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F)	
<b>Rx Product/Proprietary Name:</b> Montelukast Sodium 4mg Chewable Tablet 1000ct		<input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F)	
<b>NDC:</b> 42291-0622-10 <b>UPC:</b>		<input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F)	
<b>CVX Code:</b> <b>MVX Code:</b>		<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)	
<b>Description:</b> Montelukast Sodium 4mg Chewable Tablet 1000ct		<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)	
<b>Active Ingredients:</b>		<input type="checkbox"/> VI. Other Temperature Range Requirement (write in)	
<b>URL for Additional Product Information:</b>		<input type="checkbox"/> VII. No Requirement	
<b>Address:</b> 615 North First Street <b>State:</b> TN <b>Zip:</b> 38478		<b>b. Contact for temperature excursion questions:</b>	
<b>City:</b> Pulaski <b>Email:</b> kbracey@avkare.com		<b>Name:</b>	
<b>Key Contact:</b> Kim Bracey <b>Fax:</b> 931-292-6229		<b>Number:</b>	
<b>Phone Number:</b> 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"/>	
<b>FOR GENERIC DRUG PRODUCTS</b>		<b>c. Special regulations for product in certain states?</b>	
<b>I. Orange Book Rating:</b> AB <b>II. Brand Name:</b> Singulair®		Special returns requirements for this product? <input type="checkbox"/>	
<b>III. Generic Equivalent for Brand:</b> Montelukast Sodium		<b>d. Store product (unit of sale) upright?</b>	
		Protect product (unit of sale) from light? <input type="checkbox"/>	
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>		<b>e. Shelf life:</b> <input type="text"/> Months	
<b>Does supplier meet DSCSA definition of manufacturer?</b> Yes <b>DUNS:</b> 796560394		Initial shelf life at launch (if different): <input type="text"/> Months	
<b>Is product exempt from DSCSA?</b> No			
<b>If yes, select exemption:</b>			
<b>Other exemption - Write in:</b>			
<b>Is product repackaged?</b> Yes <b>If Yes, was original product purchased direct from mfr?</b> Yes			
<b>Is product sold by manufacturer's exclusive distributor?</b> Yes			
<b>Are any waivers granted for product ID/barcode?</b> No <b>If yes, attach documentation from FDA</b>			
<b>ADDITIONAL PRODUCT INFORMATION</b>		<b>ITEM AND PACKING INFORMATION</b>	
<b>Is the Product...</b> Direct and Drop Ship <input type="checkbox"/> No		<b>Weight Lbs.</b> <b>Dimensions (US msmts.)</b> <b>Volume (Cube)</b> <b># Pieces:</b>	
<b>Legend Device?</b> No		<b>Item:</b> 257.3g <b>Depth:</b> 5.22" <b>Height:</b> 5.22" <b>Width:</b> 2.895" <b>1</b>	
<b>State Control?</b> No		<b>Box/ Carton:</b>	
<b>ARCOS reportable?</b> No		<b>Case:</b> 20lbs <b>18.50"</b> <b>9.4375"</b> <b>12.125"</b> <b>36</b>	
<b>Co-Licensed?</b> No		<b>Pallet:</b>	
<b>Controlled Substance?</b> No		<b>UPC:</b> <b>Case:</b> <b>Carton:</b>	
<b>Schedule No.?</b> (incl. N for non-narcotic)			
<b>Controlled Substance Code:</b>			
<b>Hazardous Material/Cytotoxic Agent?</b> No			
<b>Is Item...</b>			
<b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b>			
<b>Is it reverse numbered?</b>			
<b>WHOLESALE USE ONLY:</b>		<b>COST INFORMATION</b>	
<b>Vendor #:</b>		<b>Regular Cost Per Unit of Sale (\$)</b> <b>Invoice Cost (WAC) (\$)</b> <b>Federal Excise Tax Per Unit of Sale</b>	
<b>Whsl. Code #:</b>		<b>\$509.10</b> <b>\$201.11</b>	
<b>Fineline Code:</b>		<b>As of date:</b> 8/10/16	
<b>Rx billing unit to pharmacy:</b>			
<input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter			
<b>PHARMACY ORDER / BILL UNIT</b>		<b>Other Product Information</b>	
<b>Rec. sell unit to customer?</b>		<b>Size/Strength/Form:</b> 1000ct/4mg/tablet	
<b>(Write-in, e.g. 1 Vial)</b>		<b>Product Shape:</b> round	
		<b>Product Color:</b> pink(light pink)	
		<b>Product Imprint:</b> KU;204	
<b>Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.</b>			
<b>*Please provide any additional information on page 2.</b>		<b>Signature:</b>	
<b>See new p. 3 for Designated Drop Ship Only.</b>			