



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date: 7/5/16

PRODUCT INFORMATION			
Company Name: AvKARE, INC		Application: ANDA	
Application Number for NDA/ANDA/BLA, Med Device: 90548			
Rx Product/Proprietary Name: Atorvastatin 40mg Tablet UD50			
NDC: 50268-0095-15	UPC:		
CVX Code:	MXV Code:		
Description: Atorvastatin 40mg Tablet UD50			
Active Ingredients:			
URL for Additional Product Information:			
Address: 615 North First Street		Address 2:	
City: Pulaski	State:	Zip: 38478	
Key Contact: Kim Bracey	Email: kbracey@avkare.com		
Phone Number: 931-908-0028	Fax:		
FOR GENERIC DRUG PRODUCTS			
I. Orange Book Rating: AB		II. Brand Name: Lipitor	
III. Generic Equivalent for Brand: Atorvastatin Calcium			
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 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. 0.5	
Legend Device? No	Unit of Sale Box/Carton	Dimensions (US msmts.) Depth 2.00" Height 4.25" Width 3.25"	
State Control? No	☒ Bottle	Volume (Cube) 1	
ARCOS reportable? No	☒ Box/Carton	# Pieces: 1	
Co-Licensed? No	☐ Ampule	Item: 0.5	
Controlled Substance? No	☐ Glass	Box/ Carton: 5	
Schedule No.? No	☐ Tube	Case: 9.50"	
(incl. N for non-narcotic)	☐ Vial Liquid Sgl	Pallet: 4.50"	
Controlled Substance Code:	☐ Vial Liquid Multi	UPC: Case: 5	
Hazardous Material/Cytotoxic Agent? No	☐ Vial Powder Sgl	Carton: 6.50"	
Is Item... Unit Dose	☐ Vial Powder Multi		
If Unit Dose, is item bar coded to unit dose for hospital scanning? Yes	☐ Other: Write In		
Is it reverse numbered? No			
PHARMACY ORDER / BILL UNIT		COST INFORMATION	
Rec. sell unit to customer? UD50/40mg Tablet		Regular Cost Per Unit of Sale (\$) \$26.21	
(Write-in, e.g. 1 Vial)		Invoice Cost (WAC) (\$) \$18.86	
Rx billing unit to pharmacy: Each		Federal Excise Tax Per Unit of Sale	
☐ Each	Product Shape: oval		
☐ Gram	Product Color: white		
☐ Milliliter	Product Imprint: APO:ATV/40		
		As of date: 7/5/16	

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: _____