



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

Introduction Type: New Item

Final Version

Date: 23.06.2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC)		Application: ANDA		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 217519				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in):		Store at 20 to 25 C (68 to 77 F) [see USP Controlled Room Temperature]	
DUNS: 968961354				Notes:			
Proprietary Name (If Applicable) and Established Name:				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: 55150-0470-06		Unit of Use NDC: 55150-0470-01		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
UDI:		CVX Code:		UPC: 355150470068			
Description: Tobramycin for Injection, USP 1.2 grams per Pharmacy Bulk Package(6 Vials)		MVX Code:		b. Contact for temperature excursion questions:			
Active Ingredient(s): Tobramycin				Name: Kevin Cagnetti			
URL for Additional Product Information: eugiaus.com				Number: 732.839.9400 ex 8009			
Address: 279 Princeton-Hightstown Road		Address 2:		Group E-mail: kcagnetti@EugiaUS.com			
City: East Windsor		State: NJ		Zip: 08520			
Key Contact:		Email:		c. Special regulations for product in any states? <input type="checkbox"/> No			
Phone Number: 888-238-7880		Fax: 732-355-9449		Special returns requirements for this product? <input type="checkbox"/> No			
Product Therapeutic Classification: Aminoglycoside Antibiotics				d. Store product (unit of sale) upright? <input type="checkbox"/> No			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				e. Shelf life: <input type="text" value="24"/> Months			
				Initial shelf life at launch (if different): <input type="text" value=""/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device? <input type="checkbox"/> No		Is the Product... Direct-Ship Only <input type="checkbox"/>		Size: 6 x 1.2 g Vials			
if yes, enter class #		Is the Product... Neither <input type="checkbox"/>		Strength: 1.2 grams per Pharmacy			
if yes, list NDCs of product kit?		Orphan Drug Status <input type="checkbox"/>		Dosage Form: Powder			
if yes, list NDCs of component parts reverse numbered?		FDA Approval Status <input type="text"/>		Product Shape:			
co-licensed? <input type="checkbox"/> No		Allergens Present <input type="text"/>		Product Color:			
latex-free? <input type="checkbox"/> Yes		Country of Origin: India		Product Imprint:			
preservative-free? <input type="checkbox"/> Yes							
correctional institution block? <input type="checkbox"/> No							
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No					
If Unit Dose, indicate NDC here: <input type="text"/>							
ORDER INFORMATION							
Unit of Sale				What is the NDC selling unit?			
<input checked="" type="checkbox"/> Bottle				55150-0470-06			
<input type="checkbox"/> Box/Carton				(Write-in, e.g. 1 Box of 10 Vials)			
<input type="checkbox"/> Ampule				Minimum order quantity? <input type="checkbox"/> Yes			
<input type="checkbox"/> Glass							
<input type="checkbox"/> Tube							
<input type="checkbox"/> Vial Liquid Sgl				If Yes, how many of which package type?			
<input type="checkbox"/> Vial Liquid Multi				<input type="checkbox"/> Each			
<input type="checkbox"/> Vial Powder Sgl				<input type="checkbox"/> Inner/ Carton/Pack			
<input type="checkbox"/> Vial Powder Multi				<input type="text" value="1"/> Case			
<input type="checkbox"/> Other: Write In							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? <input type="text" value="6 vials"/>				Rx billing unit to pharmacy:			
(Write-in, e.g. 1 Vial)				<input checked="" type="checkbox"/> Each			
				<input checked="" type="checkbox"/> Gram			
				<input type="checkbox"/> Milliliter			
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	1.11525	5.67	3.78	4.33	92.803	6 vials	
Box/Carton/Bundle/Inner Pack:							
Case:	10.52	12.795	8.858	9.8425	1115.530	48 vials	
Pallet:	Air-874.592	48	40	54.21	104083.20	3840 vials	
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14			
<input checked="" type="checkbox"/> Item/Each	6		00355150470068	00355150470068			
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack							
<input type="checkbox"/> Case	48		50355150470063				
<input type="checkbox"/> Pallet	3840		70355150470067				
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)		\$432.00		Whsl. Code #:			
As of date: 7/7/2023				Fineline Code:			
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: D.Venkata Surender Reddy			