



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

Version 2021

Introduction Type: New Item

Final Version

Date: 4/16/2022

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: 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): 214632		Medical Device Class, if applicable:		Temperature Range: Cold – between 2 and 8 C (36° – 46° F)		Other Temperature Range Requirement (write in): Store powder at 25°C (77°F). Excursions permitted to 15 to 30°C (59 to 86 °F)	
DUNS: 968961354		Proprietary Name (If Applicable) and Established Name: Pemetrexed for Injection		Notes:		Is this product to be shipped to customers on ice? <input type="checkbox"/> No	
Selling Unit NDC: 5150-381-01		Unit of Use NDC: 55150-381-01		UPC: 355150381012		Is this product to be shipped to customers on dry ice? <input type="checkbox"/>	
UDI:		CVX Code:		MVX Code:			
Description: Pemetrexed for Injection USP 100 mg/vial (SDV) (Mono Pack)				b. Contact for temperature excursion questions:			
Active Ingredient(s): Pemetrexed		URL for Additional Product Information:		Name: Kevin Cagnetti		Number: 732.839.9400 ex 8009	
Address: 279 Princeton-Hightstown Road		Address 2:		Group E-mail: Kcagnetti@Aurobindousa.com			
City: East Windsor		State: NJ		Zip: 08520			
Key Contact:		Email:		Special regulations for product in any states? <input type="checkbox"/> No		Special returns requirements for this product? <input type="checkbox"/> No	
Phone Number: 888-238-7880		Fax: 732-355-9449		d. Store product (unit of sale) upright? <input type="checkbox"/> No		Protect product (unit of sale) from light? <input type="checkbox"/> No	
Product Therapeutic Classification: folate analog metabolic inhibitor				e. Shelf life: Initial shelf life at launch (if different): <input type="text"/>		Months: <input type="text"/>	
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product... Direct-Ship Only <input type="checkbox"/>		Size: 1 x 10R Vial			
a legend device? <input type="checkbox"/> No		Is the Product... Neither <input type="checkbox"/>		Strength: 100 mg/vial			
if yes, enter class #		Orphan Drug Status <input type="checkbox"/>		Dosage Form: Powder			
a product kit? <input type="checkbox"/> No		FDA Approval Status		Product Shape: Vial Pack			
if yes, list NDCs of component parts		Allergens Present		Product Color:			
reverse numbered? <input type="checkbox"/> No		Country of Origin: India		Product Imprint:			
co-licensed? <input type="checkbox"/> No		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No					
latex-free? <input type="checkbox"/> Yes							
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"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AP		<input type="checkbox"/> Authorized Generic		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: ALIMTA							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN:					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP:					
If yes, select exemption:		If yes, was original product purchased direct from mfr? <input type="checkbox"/>		Provide source manufacturer for repackaged product			
Other exemption - Write in:							
Is product repackaged? <input type="checkbox"/> No							
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No							
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/>							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		1				00355150381012	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack							
<input type="checkbox"/> Case		48				50355150381017	
<input type="checkbox"/> Pallet		3072				70355150381011	
						Unit of Use GTIN-14: 00355150381012	
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost		Invoice Cost (WAC) (\$): \$376.56		Vendor #:			
As of date:				Whsl. Code #:			
				Fineline Code:			
ORDER INFORMATION							
Unit of Sale		What is the NDC selling unit?					
<input checked="" type="checkbox"/> Bottle		1 box of 1 vial					
<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		If Yes, how many of which package type?					
<input type="checkbox"/> Tube		<input type="checkbox"/> Each					
<input type="checkbox"/> Vial Liquid Sgl		<input type="checkbox"/> Inner/Carton/Pack					
<input type="checkbox"/> Vial Liquid Multi		<input type="checkbox"/> Case					
<input type="checkbox"/> Vial Powder Sgl							
<input type="checkbox"/> Vial Powder Multi							
<input type="checkbox"/> Other: Write In							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? 1 Single-Dose Vial		Rx billing unit to pharmacy:					
(Write-in, e.g. 1 Vial)		<input checked="" type="checkbox"/> Each					
		<input 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:	0.04	1.811	1.653	3.346	10.02	1	
Box/Carton/Bundle/Inner Pack:							
Case:	4.085	12.007	7.87	9.055	856.09	48	
Pallet:	359.8	48	40	54.21	104083.2	3840	
SIGNATURE AND FOOTER							
*Please provide any additional information on page 2.				Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		Signature: D.Venkata Surender Reddy	
				See new p. 3 for Designated Drop Ship Only.			