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

Version 2021 | **Introduction Type:** New Item | [ ] Final Version | **Date:** 4/16/2022

PRODUCT INFORMATION

Company Name:	AuroMedics Pharma LLC			**Application:**	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214632				
Medical Device Class, if applicable:					
DUNS:	968961354				
Proprietary Name (If Applicable) and Established Name:	Pemetrexed for Injection				
Selling Unit NDC:	5150-383-01	**Unit of Use NDC:**	55150-383-01	**UPC:**	**355150383016**
UDI		**CVX Code:**		**MVX Code:**	
Description:	Pemetrexed for Injection USP 1000 mg/vial (SDV) (Mono Pack)				
Active Ingredient(s):	Pemetrexed				
URL for Additional Product Information:					

Address:	279 Princeton-Hightstown Road			**Address 2:**	
City:	East Windsor	**State:**	NJ	**Zip:**	08520
Key Contact:		**Email:**			
Phone Number:	888-238-7880	**Fax:**	732-355-9449		
Product Therapeutic Classification:	folate analog metabolic inhibitor				

ADDITIONAL PRODUCT INFORMATION

The product is?		**Is the Product…**	Direct-Ship Only
a legend device?	No	**Is the Product…**	Neither
if yes, enter class #		**Orphan Drug Status**	
a product kit?	No		
if yes, list NDCs of component parts		**FDA Approval Status**	
reverse numbered?	No		
co-licensed?	No	**Allergens Present**	
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No	Country of Origin	India
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	No
If Unit Dose, indicate NDC here:			

PRODUCT DESCRIPTION INFORMATION

Size:	1 x 100 ml Vial
Strength:	1000 mg/vial
Dosage Form:	Powder
Product Shape:	Vial Pack
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	ALIMTA

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	**GLN:**	
Is product exempt from DSCSA?	No		
If yes, select exemption:		**GCP:**	
Other exemption - Write in:			
Is product repackaged?	No	**If yes, was original product purchased direct from mfr?**	
Is product sold by manufacturer's exclusive distributor?	No		
Has FDA granted waiver/exception/exemption for product?		**Provide source manufacturer for repackaged product**	
If yes, attach documentation from FDA.			

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00355150383016	
x	Case	48		50355150383011	
	Pallet	1152		70355150383015	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

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)
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	

b. Contact for temperature excursion questions:

Name:	Kevin Cagnetti
Number:	732.839.9400 ex 8009
Group E-mail:	Kcagnetti@Aurobindousa.com

c. Special regulations for product in any states?	No	
Special returns requirements for this product?	No	
d. Store product (unit of sale) upright?	No	
Protect product (unit of sale) from light?	No	
e. Shelf life:	24	**Months**
Initial shelf life at launch (if different):		**Months**

ORDER INFORMATION

	Unit of Sale	What is the NDC selling unit?
	Bottle	1 box of 1 vial
x	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
	Ampule	
	Glass	**Minimum order quantity?** Yes
	Tube	
	Vial Liquid Sgl	
	Vial Liquid Multi	**If Yes, how many of which package type?**
	Vial Powder Sql	Each
	Vial Power Multi	Inner/Carton/Pack
	Other: Write In	1 Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	1 Single-Dose Vial
(Write-in, e.g. 1 Vial)	

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.09	2.559	2.559	5.118	33.52	1
Box/Carton/Bundle/ Inner Pack:						
Case:	6.662	17.322	11.42	12.598	2491.45	48
Pallet:	192.92	48	40	45.16	104083.2	3840

COST INFORMATION

Regular Invoice Cost (WAC) ($)	$3,765.54
As of date:	

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
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