



# 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:	5150-382-01
Unit of Use NDC:	55150-382-01
UPC:	355150382019
UDI	
CVX Code:	
MVX Code:	
Description:	Pemetrexed for Injection USP 500 mg/vial (SDV) (Mono Pack)
Active Ingredient(s):	Pemetrexed
URL for Additional Product Information:	www.auromedics.com
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Address 2:	
Zip:	08520
Key Contact:	
Phone Number:	888-238-7880
Fax:	732-355-9449
Product Therapeutic Classification:	folate analog metabolic inhibitor

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
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?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/>
<b>b. Contact for temperature excursion questions:</b>	
Name:	Kevin Cagnetti
Number:	732.839.9400 ex 8009
Group E-mail:	Kcagnetti@Aurobindousa.com
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="checkbox"/> No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	Size: 1 x 50 ml Vial
a legend device?	<input type="checkbox"/> No	Is the Product... Neither	Strength: 500 mg/vial
if yes, enter class #		Orphan Drug Status	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
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:			

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	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="checkbox"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> 1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	ALIMTA
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 Single-Dose Vial	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
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.	
GLN:	
GCP:	
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.06	2.1653	2.1653	4.3307	20.30	1
Box/Carton/Bundle/Inner Pack:						
Case:	4.975	14.96	9.84	11.023	1622.99	48
Pallet:	232.02	48	40	52.24	104083.2	3840

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	1		00355150382019	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input type="checkbox"/> Case	48		50355150382014	
<input type="checkbox"/> Pallet	1440		70355150382018	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Invoice Cost (WAC) (\$)	\$1,882.77	Vendor #:	
As of date:		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