



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  New Item Final Version

Date: 11.06.2019

PRODUCT INFORMATION	
Company Name:	Auromedics Pharma LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	206335
DUNS:	968961354
Proprietary Name (if Applicable) and Established Name:	Tigecycline for injection, USP 50mg/vial
Selling Unit NDC:	55150-228-10
UDI	Individual Unit NDC: 55150-228-10
	CVX Code:
	MVX Code: 355150228102
Description:	Tigecycline for injection, USP 50mg in 10mL vial
Active Ingredient(s):	Tigecycline
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Temperature Range: Controlled Room – between 20 and 25 C (68° – 77°)
	Other Temperature Range Requirement (write in): Prior to Reconstitution: Store at 20°
	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"/> No
b. Contact for temperature excursion questions:	Name: _____
	Number: _____
	Group E-mail: _____
c. Special regulations for product in any states?	<input type="checkbox"/> No
	Special returns requirements for this product? <input type="checkbox"/> No
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"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="checkbox"/> No
reverse numbered?	<input type="checkbox"/> No
co-licensed?	<input type="checkbox"/> No
Is the Product... Direct-Ship Only	<input type="checkbox"/>
Is the Product... Neither	<input type="checkbox"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No

PRODUCT DESCRIPTION INFORMATION	
Size:	1 x 10's
Strength:	50mg/vial
Dosage Form:	Liquid
Product Shape:	
Product Color:	
Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 box of 10 vials
<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	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 Power Multi	<input type="checkbox"/> 1 Case
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Tygacil® for Injection, 50 mg (PF Prism [Pfizer])
	<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:
<input type="text" value="10"/> vials	<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 not, 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 a waiver/exception/exemption for product?	<input type="checkbox"/> No
GLN:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.03522	1.0098	2.2637	1.0098	2.30828593	1 vials
Box/ Carton/ Bundle/ Inner Pack:	1.464	7.13	3.19	5.75	130.782025	10 vials
Case:	3.588	8.465	7.48	6.496	411.315027	60 Vials
Pallet:	607.142	48	42.4	40	81408	1920 vials
UPC:	Case:	50355150228107				
	Carton:	00355150228102				

GTIN PRODUCT INFORMATION						
Serialized?	Level	Item	Saleable Unit	Quantity	GTIN-14	Serialized?
<input checked="" type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack		<input checked="" type="checkbox"/>	1	00355150228102	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Case		<input checked="" type="checkbox"/>	10	30355150228103	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Pallet		<input checked="" type="checkbox"/>	60	50355150228107	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	1920	70355150228101	<input checked="" type="checkbox"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$1,040.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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:

Muramreddy Penchalaiah