



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

Version 2021

Introduction Type: New Item

Final Version

Date: 4/11/2022

PRODUCT INFORMATION	
Company Name:	AuroMedics Pharma LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212825
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (if Applicable) and Established Name:	
Selling Unit NDC:	5150-337-01
UDI	
Unit of Use NDC:	55150-337-01
UPC:	355150337019
CVX Code:	
MX Code:	
Description:	Bortezomib for injection 3.5 mg /Vial [SDV] [1's]
Active Ingredient(s):	
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
Email:	
Fax:	732-355-9449
Product Therapeutic Classification:	proteasome inhibitor

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° F)
Other Temperature Range Requirement (write in)	Store at 20°C to 25°C (77°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. 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?	<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:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product...	
a legend device?	<input type="checkbox"/> No	Is the Product...	
if yes, enter class #		Orphan Drug Status	
a product kit?	<input type="checkbox"/> No	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	
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	Size:	1 x 10 ml Vial
preservative-free?	<input type="checkbox"/> Yes	Strength:	3.5 mg/vial
correctional institution block?	<input type="checkbox"/> No	Dosage Form:	Powder
opioid?	<input type="checkbox"/> No	Product Shape:	Vial Pack
Cannabinoid?	<input type="checkbox"/> No	Product Color:	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>	Product Imprint:	
If Unit Dose, indicate NDC here:			

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 box of 1 vial
<input checked="" 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"/> Tube	<input type="checkbox"/> Yes
<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 Power Multi	<input type="checkbox"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Velcade for Injection
	<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:	0.07532	1.81	1.65	3.35	10.00	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	6.125	12.598	8.47	9.842	1049.57	48
Pallet:	523.03	48	40	54.21	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		00355150337019	00355150337019
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input type="checkbox"/> Case	48		50355150337014	
<input type="checkbox"/> Pallet	3840		70355150337018	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Invoice Cost (WAC) (\$)	761.41	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