



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

Version 2020 Introduction Type:  New Item  Final Version Date:

PRODUCT INFORMATION	
Company Name:	Auromedics LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214575
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Docetaxel Injection
Selling Unit NDC:	55150-378-01
Unit of Use NDC:	55150-378-01
UPC:	355150378012
CVX Code:	
MXV Code:	
Description:	Docetaxel Injection, USP 20 mg per 2 mL (10 mg/mL) One 2 mL Single-Dose Vial
Active Ingredient(s):	Docetaxel Injection
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Zip:	08520
Key Contact:	
Phone Number:	
Product Therapeutic Classification:	Antineoplastic agent, taxoid

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	Store at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature].
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
<b>b. Contact for temperature excursion questions:</b>	
Name:	Steve Lucas
Number:	732-823-4122
Group E-mail:	slucas@aurobindousa.com
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	No	Is the Product... Direct-Ship Only	1 x 2 mL Single-Dose Vials
a product kit? if yes, list NDCs of component parts	No	Orphan Drug Status	Neither
reverse numbered?	No	FDA Approval Status	20 mg per 2 mL
co-licensed?	No	Allergens Present	Liquid
latex-free?	Yes	Country of Origin	Vial pack
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	
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 (55150-378-01)
<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? 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	Each
<input type="checkbox"/> Vial Power Multi	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?:	Taxotere®
<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 Vial	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Case/Bundle/Inner Pack:						
Case:	4.897	11.22	7.67	8.2	705.67068	48
Pallet:	620.709	48	40	54.61	104851.2	5760

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150378012	
<input type="checkbox"/> Box/Case/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		50355150378017	
<input checked="" type="checkbox"/> Pallet	5760		70355150378011	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$68.50	Whsl. Code #:	
As of date:		Fineline Code:	



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PRODUCT INFORMATION	
Company Name:	Auromedics LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214575
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Docetaxel Injection
Selling Unit NDC:	55150-379-01
Unit of Use NDC:	55150-379-01
UPC:	355150379019
CVX Code:	
MXV Code:	
Description:	Docetaxel Injection, USP 80 mg per 8 mL (10 mg/mL) One 8 mL Multi-Dose Vial
Active Ingredient(s):	Docetaxel Injection
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Zip:	08520
Key Contact:	
Phone Number:	
Product Therapeutic Classification:	Antineoplastic agent, taxoid

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	Store at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature].
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
<b>b. Contact for temperature excursion questions:</b>	
Name:	Steve Lucas
Number:	732-823-4122
Group E-mail:	slucas@aurobindousa.com
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	No	Is the Product... Direct-Ship Only	1 x 8 mL Multi-Dose Vials
if yes, list NDCs of component parts reverse numbered?	No	Is the Product... Orphan Drug Status	Neither
co-licensed?	No	FDA Approval Status	80 mg per 8 mL
latex-free?	No	Allergens Present	Liquid
preservative-free?	Yes	Country of Origin	India
correctional institution block?	No	Is this product covered under the Trade Agreements Act (TAA)?	
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
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 (55150-378-01)
<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? 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	Each
<input type="checkbox"/> Vial Power Multi	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?:	Taxotere®
<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 Vial	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:						
Case:	6.712	12.598	8.465	9.843	1049.6779	48
Pallet:	569.981	48	40	54.21	104083.2	3840

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150379019	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	48		50355150379014	
<input checked="" type="checkbox"/> Pallet	3840		70355150379018	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$205.00	Whsl. Code #:	
As of date:		Fineline Code:	



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PRODUCT INFORMATION	
Company Name:	Auromedics LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214575
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Docetaxel Injection
Selling Unit NDC:	55150-380-01
Unit of Use NDC:	55150-380-01
UPC:	355150380015
CVX Code:	
MXV Code:	
Description:	Docetaxel Injection, USP 160 mg per 16 mL (10 mg/mL) One 16 mL Multi-Dose Vial
Active Ingredient(s):	Docetaxel Injection
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Zip:	08520
Key Contact:	
Phone Number:	
Product Therapeutic Classification:	Antineoplastic agent, taxoid

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	Store at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature].
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
<b>b. Contact for temperature excursion questions:</b>	
Name:	Steve Lucas
Number:	732-823-4122
Group E-mail:	slucas@aurobindousa.com
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	No	Is the Product... Direct-Ship Only	1 x 16 mL Multi-Dose Vials
if yes, list NDCs of component parts reverse numbered?	No	Is the Product... Orphan Drug Status	160 mg per 16 mL
co-licensed?	No	FDA Approval Status	Liquid
latex-free?	No	Allergens Present	
preservative-free?	Yes	Country of Origin	Vial pack
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	
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 (55150-378-01)
<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? 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="text"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Taxotere®
<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 Vial	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:						
Case:	6.712	12.598	8.465	9.843	1049.6779	48
Pallet:	569.981	48	40	54.21	104083.2	3840

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150380015	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		50355150380010	
<input checked="" type="checkbox"/> Pallet	3840		70355150380014	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$320.00	Whsl. Code #:	
As of date:		Fineline Code:	