

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

Version 2020						Introduction Type:	New Item]	Fi	inal Version			Date:	8/11/2	2021		
PRODUCT INFORMATION										SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*				
Company Name:	Application:	ANDA	a. Temperature – Indicate the USP temperature range for this product.														
Application Number for NDA/AN	DA/BLA (drug); PM	A/510(k)(med devi	ce):	214	575		*	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
DUNS:	968961354								Other Temp	to 25°C (68°	25°C (68° to 77°F) [see						
Proprietary Name (If Applicable) a	nd Established Nar	ne: Docetax	el Injection						(write		•	USP Control	led Room Te	mperature].			
Selling Unit NDC:					55150-378-01	UPC: 35515		Notes									
UDI			CVX Code:			MVX Code:		1									
Description: Docetaxel Injection, USP 20 mg per 2 mL (10 mg/mL) One 2 mL Single-Dose Vial											to customers on ic			No			
Destand Intelle										uct to be shipped	to customers on d	ry ice?		No			
Active Ingredient(s): Docetaxel Injection										ro excursion au	netione:						
URL for Additional Product Information:									b. Contact for temperature excursion questions: Name: Steve Lucas								
Address:	279 Princeton-High	tstown Road			,	Address 2:		11	732-823-4122								
City:	East Windsor				State:	NJ Zip:	08520		Group E-m	nail:		slucas@aurobindousa.com					
Key Contact:					Email:												
Phone Number:					Fax:			c. Special reg		product in any		No					
Product Therapeutic Classification	n:	Antineoplastic agent	t, taxoid						Special retu	urns requirements	s for this product?	No					
	ADDITION	IAL PRODUCT INF	ODMATION			DRODUCT DESC	RIPTION INFORMATION			!->!!-40							
	ADDITION	IAL PRODUCT INF				PRODUCT DESC	RIFTION INFORMATION	d. Store prod									
The product is?		NI-	Is the Product	Direct-Ship O	nly		1 x 2 mL Single-Dose	a Chalf life.	Protect pro	oduct (unit of sa	le) from light?			24	Months		
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	Vials	e. Shelf life:	Initial chalf	f life at launch (i	f different):	24			Months		
a product kit?		No	Orphian Drug Status				20 mg per 2 mL		illitiai sileli	i ilie at laulicii (i	i dilierentj.				Months		
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFORM	IATION					
component parts						Dosage Form:	Liquid										
reverse numbered?		No				200490 . 0			Unit of Sal			What is the					
co-licensed? latex-free?		No	Allergens Present				Vial pack			ottle ox/Carton		1 Box of 1 V	al (55150-37) g. 1 Box of 10				
preservative-free?		Yes Yes				Product Shape:	viai pack			mpule		(vvrite-iri, e.	g. i box oi it) viais)			
correctional institution block?		No								lass		Minimum o	der quantity	?	Yes		
opioid?	_	No				Product Color:				ube				-			
Cannabinoid?		No	Country of Origin	India		Product Imprint:				ial Liquid Sgl							
If Unit Dose, is item bar coded to unit dose for hospital								Vial Liquid Multi If Yes, how many of which pack Vial Powder Sql Each						ch package t	ype?		
scanning? Is this product covered under the If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)?								Each Inner/Carton/Pack									
If Unit Dose, indicate NDC here:										ial Power Multi ther: Write In		1	Inner/Carton Case	Pack			
			FOR GENERIC DRUG PRO	ODUCTS						uici. Wiite iii			Ouse				
			TOR GENERIO BROOT R	350010					<u> </u>			1					
					Autho	rized Generic *If Aut	horized Generic, other section			PHA	ARMACY ORDER	/ BILL UNIT					
I. Orange Book Rating:	AP			1		fields	are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:									
II. Generic Equivalent to What Bra	ind?:	Taxotere®							1 Vial			x Each					
							(Write-in, e.g.	•	Gram								
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	MATION							х	Milliliter				
Does supplier meet DSCSA definit	tion of manufacture	ar?	Yes	GL	u.				_	ITEM	AND PACKING IN	IFORMATIO	ı		_		
Is product exempt from DSCSA?	tion of manufacture		No	_	١.						AND I ACITING II	II ORMATIO	•				
If yes, select exemption:				_				-			Dimensio	ons (US msn	ite \	Volume			
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:		
Is product repackaged?	L		No	If Y	es, was origin	al product purchased		Item/Each:		0.06	1.574	1.496	2.559	6.0256875	1		
Is product sold by manufacturer's			No	_	ect from mfr?					0.00	1.574	1.490	2.559	0.0230673	'		
Has FDA granted waiver/exception	n/exemption for pro	oduct?	No	If y	es, attach doc	umentation from FDA.		Box/Carton/B	undle/					1			
		CTIN	AND HIBCC PRODUCT IN	IEODMATION				Inner Pack: Case:									
		GTIN	AND HIBCC PRODUCT II	IFORWATION				Case.		4.897	11.22	7.67	8.2	705.67068	48		
Saleable Unit of Measure		Quantity	HIBCC		GTIN-1	4	Unit of Use GTIN-14	Pallet:									
X Item/Each	Г	1				150378012				620.709	48	40	54.61	104851.2	5760		
Box/Carton/Bundle/Inner Pack																	
X Case		48				50378017			COSTI	NFORMATION		١	WHOLESALE	ER USE ONLY	Y:		
x Pallet	Pallet 5760 70355150378011							Regular Cost		ĺ		Vendor #:					
	 										\$68.50	Whsl. Code	#-				
								1170.00 3031	Invoice Cost (WAC) (\$) \$68.50 Whsl. Code #: Fineline Code:								
] [As of date:]					
1								Ш				L					
			Attach conv of CAEETV DA	TA SHEET (SD)	S) or non hazai	rd lotter DACKACE INICE	ERT LAREL AND PHOTO OF	DRUDITICT DACK	ACING and	BARCODE							



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Version 2020				Introduction ¹	Type:	New Item			Final Version			Date:	8/11/2	2021			
PRODUCT INFORMATION										SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*				
Company Name: Auromedics LLC Application: ANDA									a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k)(med device):	2	14575	•	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)											
DUNS:	968961354						mperature Range F	Requirement	Store at 20°	to 25°C (68°	to 77°F) [see						
Proprietary Name (If Applicable) a								ite in)	•	USP Control	led Room Te	mperature].					
Selling Unit NDC:	55150-379-01	Unit of Us	NDC:	55150-379-01		3551503	79019		Notes								
UDI		CVX Cod	e:		MVX Code:			<u>.</u>									
Description:	Docetaxel Injection, USP 8	30 mg per 8 mL (10 mg/mL) One	8 mL Multi-Dose Vial						Is this pro	oduct to be shipped	to customers on ic	ce?		No			
									Is this pro	oduct to be shipped	to customers on d	ry ice?		No			
Active Ingredient(s): Docetaxel Injection																	
URL for Additional Product Inform										ture excursion que	Steve Lucas						
Address:	279 Princeton-Hightstown	Road			Address 2:			-11	:		732-823-4122						
City:	East Windsor	11000		State:	NJ	Zip:	08520	11	- -mail:		slucas@aurobindousa.com						
Key Contact:				Email:													
Phone Number:				Fax:				c. Special re	gulations f	for product in any	states?						
Product Therapeutic Classification	n: Antine	pplastic agent, taxoid						_	Special r	eturns requirements	s for this product?						
	ADDITIONAL PR	ODUCT INFORMATION			PRODUCT	DESCRI	PTION INFORMATION	d. Store pro	duct (unit d	of sale) upright?							
The product is?		Is the Product	Direct-Ship	Only					Protect	product (unit of sa	le) from light?						
a legend device?	No	Is the Product	Neither		Size:	1 x 8 mL Multi-Dose		e. Shelf life:				24			Months		
if yes, enter class #		Orphan Drug St	ntus		Size.	[Vials		Initial sh	nelf life at launch (i	f different):				Months		
a product kit?	No				Strength:	ŀ	80 mg per 8 mL										
if yes, list NDCs of		FDA Approval S	tatus			Ļ	Limital				ORDER INFORM	IATION					
component parts reverse numbered?	No				Dosage For	m:	Liquid		Unit of S	Sala		What is the	NDC selling	unit2			
co-licensed?	No	Allergens Prese	nt			L				Bottle			al (55150-37				
latex-free?	Yes	7				F	Vial pack		x	Box/Carton			g. 1 Box of 10				
preservative-free?	Yes		Product Sha	ape:	,			Ampule	,g								
correctional institution block?	No			lor:			Glass		Minimum order quantity? Yes								
opioid?	No		Product Col	Ю.			Tube										
Cannabinoid? No Country of Origin India					Product Imp	orint:			Vial Liquid Sgl								
If Unit Dose, is item bar coded to u	init dose for hospital	Is this product co	ranad rindon tha		L			Vial Liquid Multi	If Yes, how many of which package type?								
scanning? If Unit Dose, indicate NDC here:						Vial Powder Sql Vial Power Multi	Each Inner/Carton/Pack										
If Unit Dose, Indicate NDC here:		Trade Agreemen	s Act (IAA):							Other: Write In		1	inner/Carton Case	/Pack			
		FOR GENERIC DE	IIG PPODIICTS							Outer: Write iii		<u> </u>	Ousc				
		TOR GENERIO DI	DO FRODUCTS									1					
				Autho	rized Generic	*If Author	rized Generic, other section			PHA	ARMACY ORDER	/ BILL UNIT					
I. Orange Book Rating:	AP					fields are	e not applicable	Rec. sell uni	t to custon	ner?		Rx billing u	nit to pharm	acv:			
II. Generic Equivalent to What Bra	and?: Taxote	re®							I		x Each						
-								(Write-in, e.c	g. 1 Vial)				Gram				
	DR	UG SUPPLY CHAIN SECURIT	ACT (DSCSA) INFO	RMATION								X	Milliliter				
Does supplier meet DSCSA definit	tion of manufacture-2	Yes	^	iLN:				1		ITEM	AND PACKING I	JEORMATIO	· .	<u> </u>			
Is product exempt from DSCSA?	nion of manufacturer?	No Yes		ILIV.						TIEW	AND PACKING II	W OKWATIO	<u> </u>				
If yes, select exemption:]			Dimore!	ons (US msn	nte \	Volume			
Other exemption - Write in:							1			Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:		
Is product repackaged?		No	If	Yes, was origin	nal product purch	ased	_	Item/Each:						<u> </u>			
Is product sold by manufacturer's	exclusive distributor?	No		irect from mfr?						0.1	1.811	1.653	3.346	10.016529	1		
Has FDA granted waiver/exception	n/exemption for product?	No	If	yes, attach doo	umentation from	FDA.		Box/Carton/	Bundle/								
								Inner Pack:									
		GTIN AND HIBCC PRO	DUCT INFORMATION	ı				Case:		6.712	12.598	8.465	9.843	1049.6779	48		
Onlankia ilinik af Mari	<u>.</u>			O.T			OTN:	III Ballata						,			
Saleable Unit of Measure	Quanti	y HIBCC		GTIN-1		i	Unit of Use GTIN-14	Pallet:		569.981	48	40	54.21	104083.2	3840		
X Item/Each Box/Carton/Bundle/Inner Pack	1			00355	150379019												
X Case	48			503551	150379014				cos	T INFORMATION		1	WHOLESALI	ER USE ONL	Y:		
x Case 46 50335150 x Pallet 3840 70355150														OLLSALER USE UNLT:			
·					Regular Cos	t			Vendor #:								
												-					
								Invoice Cost	t (WAC) (\$))	\$205.00	Whsl. Code					
									t (WAC) (\$))	\$205.00	Whsl. Code Fineline Co					
								As of date:	t (WAC) (\$)		\$205.00						
							RT, LABEL AND PHOTO OF	As of date:			\$205.00						



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Version 2020						Introduction Type:	New Item]	F	inal Version			Date:	8/11/	2021			
			PRODUCT INFORMAT	TION					•	SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*					
Company Name:	Auromedics LLC Application: ANDA NDA/BLA (drug); PMA/510(k)(med device): 214575								a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN	DA/BLA (drug); PMA	•	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)															
DUNS:	968961354 e) and Established Name: Docetaxel Injection									nperature Range R	Requirement			to 77°F) [see				
Proprietary Name (If Applicable) a				(write	e in)		USP Controlled Room Temperature].											
Selling Unit NDC: UDI	55150-380-01		Unit of Use NDC: CVX Code:		55150-380-01	UPC: 35515 MVX Code:	0380015		Notes									
	5	1100 100	-1			INVX Code.		<u> </u>										
Description: Docetaxel Injection, USP 160 mg per 16 mL (10 mg/mL) One 16 mL Multi-Dose Vial											to customers on ic to customers on di			No No				
Active Ingredient(s): Docetaxel Injection								11	is tills proc	addi to be shipped	to customers on u	ry ice :		INO				
									b. Contact for temperature excursion questions:									
URL for Additional Product Inforn								Name: Steve Lucas										
Address:	279 Princeton-Hights East Windsor	town Road			State:	Address 2: NJ Zip:	08520	1	Number: Group E-r			732-823-4122 slucas@aurobindousa.com						
City: Key Contact:	East Willusui				Email:	NJ ZIP:	06320	1	Group E-I	nan:		siucas@aurobindousa.com						
Phone Number:					Fax:			c. Special reg	ulations fo	r product in any	states?							
Product Therapeutic Classification	n: A	ntineoplastic agen	nt, taxoid		1			' '		turns requirements								
	ADDITIONA	AL PRODUCT INF	ORMATION			PRODUCT DESCI	RIPTION INFORMATION	d. Store prod	uct (unit of	sale) upright?								
The product is?			Is the Product	Direct-Ship C	nly				Protect pr	roduct (unit of sa	le) from light?							
a legend device?	N	lo	Is the Product	Neither		Size:	1 x 16 mL Multi-Dose	e. Shelf life:						24	Months			
if yes, enter class #			Orphan Drug Status			0.20.	Vials		Initial she	If life at launch (i	f different):				Months			
a product kit? if yes, list NDCs of	No Strength: 160 mg per 16 mL										ORDER INFORM	IATION						
component parts			FDA Approval Status				Liquid				ORDER IN ORM	ATION						
reverse numbered?	N	lo				Dosage Form:	•		Unit of Sa	ile		What is the	NDC selling	unit?				
co-licensed?	N	lo	Allergens Present						E	Bottle		1 Box of 1 V	al (55150-37	8-01)				
latex-free?		'es				Product Shape:	Vial pack			Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)				
preservative-free? correctional institution block?		'es								Ampule				•				
opioid?	_	lo lo				Product Color:				Glass Tube		Minimum o	der quantity		Yes			
Cannabinoid?		lo	Country of Origin	India						/ial Liquid Sgl								
If Unit Dose, is item bar coded to u			, , ,			Product Imprint:				/ial Liquid Multi		If Yes, how	many of whi	ch package t	type?			
scanning?			Is this product covered up					Vial Powder Sql Each										
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?				Vial Power Multi				Inner/Carton/Pack						
								<u> </u>		Other: Write In		1	Case					
			FOR GENERIC DRUG PR	DDUCTS					L									
					Author	rized Generic *If Autl	horized Generic, other section	PHARMACY ORDER / BILL UNIT										
I. Orange Book Rating:	AP			7			are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:										
II. Generic Equivalent to What Bra	, ··	axotere®						1 Rec. sen unit	U1.	x Each								
•	_							(Write-in, e.g.	1	Gram								
		DRUG SUPPLY	Y CHAIN SECURITY ACT (DSCSA) INFOR	RMATION							х	Milliliter					
Does supplier meet DSCSA defini	tion of manufacture	•2	Yes	GL	N·					ITEM	AND PACKING IN	IEORMATIO						
Is product exempt from DSCSA?	ition of manufacturer	· —	No	_	N.					11 E.W	AND FACKING IN	II OKWATIOI	•					
If yes, select exemption:	_			_				"			Dimoneio	ons (US msn	ite \	Volume				
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:			
Is product repackaged?	_		No	If Y	'es, was origin	al product purchased		Item/Each:		0.1	1.811	1.653	3.543	10.606265	1			
Is product sold by manufacturer's			No		ect from mfr?					0.1	1.011	1.000	3.543	10.000203	'			
Has FDA granted waiver/exception	n/exemption for prod	luct?	No	If y	es, attach doc	umentation from FDA.		Box/Carton/B	Bundle/									
		CTIN	I AND HIBCC PRODUCT IN	IEODMATION				Inner Pack: Case:										
		GIIN	AND HIBCC PRODUCT II	IFORMATION				Case.		6.712	12.598	8.465	9.843	1049.6779	48			
Saleable Unit of Measure	Q	Quantity	HIBCC		GTIN-1	4	Unit of Use GTIN-14	Pallet:		500.004	40		F4.04	404000 0	00.10			
x Item/Each		1				50380015		<u> </u>		569.981	48	40	54.21	104083.2	3840			
Box/Carton/Bundle/Inner Pack																		
X Case		48				50380010			COST	INFORMATION		١	WHOLESALE	ER USE ONL	Y:			
x Pallet	, F	3840			703551	50380014		Regular Cost V										
	┪				+							Vendor #: Whsl. Code	#:					
	1											Fineline Co						
								As of date:										
<u> </u>				TA 0115== ::-	٠. :		-DT ADEL AND	DDODUST TO				l .						