

CHDMA Standard Pharmaceutical Product Information

Now Itom	Promotion/Deal Open Stock	Post Launch Chango	Date:	
ivew item	Promotion/Dear Deen Stock	rost Laurion change		

Final Version

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PRODUCT INFORMATION					SPECIAL HANDLING AND STORAGE REQUIREMENTS*								
Company Name:	Name: AuroMedics Pharma LLC			NDA A	NDA BLA Med Device 7	a. Tempera	erature – Indicate the USP temperature range for this product.						
Application number for NDA/ ANDA/ BLA, Med Device:						I. Freezer – between -25 and -10 C (-13° – 14° F)							
Rx Product / Proprietary Name: Acyclovir Sodium Injection 500 mg/10 mL						☐ II. Cold – between 2 and 8 C (36° – 46° F)							
NDC:	55150-154-10	U	JPC:				III. Cool – bet	tween 8 and 1	15 C (46° – 59	9° F)			
	CVX Code:	M	/IVX Code:			✓	IV. Controlle	d Room – bet	ween 20 and	1 25 C (68° – 1	77° F)		
Description:	Acyclovir Sodium Injection	500 mg/10	mL (10x10 m	L SDV)			allows for excursions between 15 and 30 C (59° – 86° F)						
							V. Avoid Exc	essive Heat -	above 40 C	(>104° F)			
Active inc	gredients:						VI. Other Ter	mperature Ra	ınge Require	ment			
								(write in)					
JRL for additional	product information:						VII. No Requi	irement					
Address:	6 Wheeling Road			Address 2:		b. Contact	for temperatu	re excursion	questions:				
City:	Dayton, NJ 08810	State:		Zip:		Name:	: <u></u>			Number:			
Key Contact:			Email:										
Phone Number:			Fax:			Is this p	roduct to be sl	hipped to cus	stomers on ic	e?	\bigcirc Yes	○ No	
	FOR	GENERIC	DRUG PROD	DUCTS		Is this p	roduct to be sl	hipped to cus	tomers on d	ry ice?	○ Yes	○ No	
. Orange Book Ra		II. Brand I	Name:										
II. Generic Equiva						c. Special ı	regulations for	r this product	in certain st	ates?	○ *Ye	s O No	
	ADDITI	ONAL PRO	DUCT INFO	RMATION		Special ı	returns require	ements for th	is product?		○ *Ye	s O No	
	Leve	el H	low?		GTIN-14								
Serialized?	○ Yes ○ No ☐ Iten	n 🗌 2D	Linear	RFID		d. Store pi	roduct (unit of	sale) upright	:?		○ Yes	○ No	
	Cas	_	Linear	RFID	50355150154109	Protect	product (unit	of sale) from	light?		○ Yes	○ No	
	Pall	et2D	Linear	RFID	70355150154103				-				
s the Product	Direct Ship Item	Direct and	Dron Shin	Drop Shin	o only item (See new page 3.)	e. Shelf life			Months		1	1	
		_ Direct and	Drop Stilp		of the fire (See New Page 3.)		Initial shelf li	fe at launch (if different):			Months	
Legend Device?	0 103 0 110				ITEM ANI	D PACKING	INFORMATIO	ON					
a State Control? ARCOS reportable	O Yes O No			Order Info	rmatian			Dimensions (US msmts.)				Malaura -	
Co-Licensed?	Q 163 Q 140	Unit	of Sale	What is the ND		\dashv	Weight Lbs.	Depth	Height	Width:	Volume (Cube)	# Pieces:	
Repackaged?	○ Yes ○ No ○ Yes ○ No	Bottle		1 Box of 10 Via	-			1			(Cube)		
Controlled Substa		Box / C		1 Box of 10 via		Item:					0		
Schedule No.?	Thes I NO	Ampule	e	(Wri	te-in, e.g. 1 Box of 10 Vials)	Box/	0.00	F 6 4 5	0.000	0.405	07.4=0.4=	40	
	(incl. N for non-narcotic	c) Glass	Ī	Minimum orde		Carton:	0.62	5.315	2.362	2.165	27.17947	10 vials	
		Tube		If Vac how ma	ny of which package type?	Case:	17.73	14.173	6.339	11.614	1043.433	240 vials	
Hazardous Materia	al / Cytotoxic Agent?	1 -	quiu ogi	ii res, now ma	ny or willen package type?	Case.	17.73	14.173	0.559	11.014	1043.433	(4x6x10 vials)	
	○ *Yes ○ No		quid Multil owder Sal		☐ Eac	Pallet:	994.58	47.2441	47.441	39.3701	88240 40	54 shippers	
s Item O Unit	Dose Unit of Use		owder Syl owder Multi		☐ Inner / Carton	i anet.	334.30	77.2771	47.441	39.3701	00240.43	or silippers	
	par coded to unit dose for		Write In		Case	UPC:	Case:						
nospital scanning?	○ Yes ○ No						Carton:						
		RMACY ORDER / BILL UNIT Other Product Information			ion				COST INFORMATION				
		Rec. sell u	ell unit to customer? Size/Strength/Form:				Regular Cos		Invoice Co	st (WAC) (\$)	Federal Excise Tax Per		
WHOLESALER USE ONLY:							Sale	e (\$)		(/(+/	Unit of Sale	•	
/endor #:			(Write-in, e.g. 1 Vial)		Product Shape:								
Whsl. Code #:		Rx billing unit to pharmacy:			Product Color:								
ineline Code:		Each	Gram	Millilite	Product Imprint:								



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New Item	Promotion/Deal Open Stock	Post Launch Change	Date:	
LINGW HEITI	Fluillottott/Deat Open Stock	i ost Laurien change		

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PRODUCT INFORMATION					SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
Company Name:	me: AuroMedics Pharma LLC				NDA ANDA BLA Med Device 7 a.			a. Temperature – Indicate the USP temperature range for this product.						
	Application number for NDA/ ANDA/ BLA, Med Device:			vice:		I. Freezer – between -25 and -10 C (-13° – 14° F)								
Rx Product / Proprietary Name: Acyclovir Sodium Injection 1000 mg/20 mL						II. Cold – between 2 and 8 C (36° – 46° F)								
	55150-155-20		UPC:			7 7	III. Cool – bet		•	•				
	CVX Code:		MVX Cod	e:			IV. Controlled		•	•	77° F)			
Description:		n Injection	1000 mg/20 mL (10					cursions bety		•	•			
	, , , , , , , , , , , , , , , , , , , ,	,	(essive Heat -		•	,,			
Active inc	gredients:							mperature Ra		` '				
Active ing	greaterits.						VI. Other rei	(write in)	nge Require	mem				
URL for additional	product informat	ioni					VII. No Regui	` ,						
				Addross 2	.1		•							
Address:	6 Wheeling Road		lo	Address 2:			for temperatu	re excursion	questions:					
City:	Dayton, NJ 0881	U	State:	Zip:		Name:				Number:				
Key Contact:				nail:		_								
Phone Number:				Fax:		-	roduct to be sl				○ Yes	○ No		
		FOR (GENERIC DRUG	PRODUCTS		Is this p	roduct to be sl	nipped to cus	tomers on d	ry ice?	○ Yes	○ No		
I. Orange Book Rat	_		II. Brand Name:											
III. Generic Equival	lent for Brand:					c. Special ı	regulations for	r this product	in certain st	ates?	○ *Ye	s O No		
		ADDITIO	NAL PRODUCT I	NFORMATION		Special ı	returns require	ements for th	is product?		○ *Ye	s O No		
		Level	How?		GTIN-14									
Serialized?	O Yes O No	Item	🗌 2D 🔲 Li	near 🗌 RFID		d. Store pi	roduct (unit of	sale) upright	?		○ Yes	○ No		
		Case	🗌 2D 🔲 Li	near 🗌 RFID	50355150155205	Protect	product (unit	of sale) from	light?		○ Yes	_		
		Pallet	2D Li	near 🗌 RFID	70355150155209									
Is the Product			1			e. Shelf life	e:		Months					
	Direct Ship It	tem	Direct and Drop Shi	p Drop Ship	o only item (See new page 3.)		Initial shelf li	fe at launch (if different):			Months		
a Legend Device?	○ Yes	○ No			ITEM AN	ID BACKING	INFORMATIO	NI.						
a State Control?	○ Yes	○ No			HEWAN	DPACKING	INFORMATIC)N						
ARCOS reportable	? O Yes	\bigcirc No		Order Info	ormation		Weight Lbs.		sions (US m		Volume	# Pieces:		
Co-Licensed?	O Yes	○ No	Unit of Sale	What is the ND	C selling unit?		Weight Lbs.	Depth	Height	Width:	(Cube)	# Fieces.		
Repackaged?	O Yes	\bigcirc No	Bottle	1 Box of 10 Via	ıls	Item:					0			
Controlled Substar	nce? O Yes	O No	Box / Carton			item.					U			
Schedule No.?			Ampule	(Wr	ite-in, e.g. 1 Box of 10 Vials)	Box/	1.075	6.496	2.755	2.677	47.90888	10 vials		
	(incl. N for n	on-narcotic)		Minimum orde	er quantity? \bigcirc Yes \bigcirc No	Carton:	1.070	0.400	2.700	2.077	47.00000	10 Viais		
			U Tube ✓ Vial Liquid Sql	If Yes, how ma	iny of which package type?	Case:	13.77	14.173	4.33	14.173	869.7841	100 vials		
Hazardous Materia		_	Vial Liquid Sgi	•			10				00011011	2x5x10 vials		
	○ *Yes	○ No	Vial Powder Sql	'	_ Eac	Pallet:	698.54	47.2441	45.472	39.3701	84578.14	48 shippers		
Is Item O Unit	: Dose O Unit o	of Use	Vial Powder Mu	ti	Inner / Carton	r unot:	000.04	77.2771	40.472	00.0701	04070.14	40 Shippers		
If Unit Dose, is item b	oar coded to unit d	ose for	Other: Write In		Case	UPC:	Case:							
hospital scanning?	O Yes	\bigcirc No				or c.	Carton:							
ls it reverse numbe	ered? O Yes	○ No	PHARMACY O	RDER / BILL UNIT	Other Product Informati	ion			COST INFO	RMATION				
Rec. sell unit to cust			stomer?	Size/Strength/Form:	Regular Cost Per Unit of Invoice Cost (WAC)			et (\M\AC\ (\$\	Federal Excise Tax Per					
WHOLESALER USE ONLY:							Sale	e (\$)	invoice Co	or (AAMC) (4)	(WAC) (\$) Unit of Sale			
Vendor #:			(Write-in	, e.g. 1 Vial)	Product Shape:									
Whsl. Code #:		Rx billing unit to p	•											
Fineline Code:			Each Gra		Product Imprint:									
			•		•						•			

Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.