

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

				Introduction Type:	New Item	X	Final Version			Date:	02.12	2021	
		PRODUCT INFORMATION					SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*			
Company Name: Strides Pharma Inc.				Application:	ANDA	a Temperature – Inc	dicate the USP tempe	erature range for t	this product				
Application Number for NDA/AN		(med device):	Аррисацон.	ANDA	a. Temperature – Indicate the USP temperature range for this product.  Temperature Range  Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applica		inica actiocj.	75671			Топро	crature range	CONTROLLED TROUT	DOLWOON 20	una 20 0 (0	<del>5 11 1)</del>		
DUNS:	11-8344-504					Othor	Temperature Range F	Poquiromont	Controlled R	oom – hetwe	een 20 and 25	5 C (68° –	
Proprietary Name (If Applicable)		Megestrol Acetate Oral Suspension, US	SP 480ml 16				write in)	•	77°	oom – betwe	en 20 and 25	, C (00 –	
Selling Unit NDC:	64380-0160-02	Unit of Use NDC:	51 400IIIL 10	UPC: 3643	8800160021	Notes	,						
UDI	04300-0100-02	CVX Code:		MVX Code:	1000100021	Notes							
Description:	Milky white, lemon-lime flavo	red oral suspension.					product to be shipped				No	-	
1	1.0					Is this	product to be shipped	I to customers on o	dry ice?		No	I	
Active Ingredient(s):	Megestrol	Acetate											
		1-9	.1.66211.6.60	7 . 40 200 440 0004	201-1454452	b. Contact for temperature excursion questions:							
URL for Additional Product Infor	2 Tower Center Blvd	dailymed.nlm.nih.gov/dailymed/dru	iginto.ctm?setia=ta9/			Name: Number:			Michael Gargiulo 609-773-5004				
Address:	East Brunswick		State:		e 1102 : 08816	1			609-773-5004				
City:	Walt Busbee		Email:	-	vice@stridesusa.com	Group E-mail:							
Key Contact: Phone Number:	609-773-5008		Fax:	609-935-0806	vice@stridesusa.com	C Special regulation	ne for product in any	states?			No	1	
				009-933-0000		c. Special regulations for product in any states?  Special returns requirements for this							
Product Therapeutic Classification	on:					Specia	ai returns requirement	s for this product?			No	l .	
	ADDITIONAL DDG	DUOT INFORMATION		PROPUST PESSE	DIDTION INFORMATION	ıl.a						I	
	ADDITIONAL PRO	DUCT INFORMATION		PRODUCT DESCR	RIPTION INFORMATION	d. Store product (un	it of sale) upright?				No	<u>I</u>	
The product is?		Is the Product				Protec	ct product (unit of sa	le) from light?			No		
a legend device?	No	Is the Product		Size:	16	e. Shelf life:					36	Months	
if yes, enter class #		Orphan Drug Status		Oizo.		Initial	shelf life at launch (i	f different):			24	Months	
a product kit?	I Strength.												
if yes, list NDCs of		FDA Approval Status						ORDER INFORM	ATION				
component parts				Dosage Form:	Milliter	II							
reverse numbered?						Unit o			What is the		unit?		
co-licensed?	No	Allergens Present			N1/A	x	Bottle		BOTTLE of		10.15		
latex-free?				Product Shape:	N/A		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Viais)		
preservative-free? correctional institution block?					White (miller, white)		Ampule		Minimum			Voc	
opioid?				Product Color:	White (milky white)	II —	Glass Tube		Minimum or	der quantity	/ [	Yes	
Cannabinoid?		Country of Origin			N/A	II —	Vial Liquid Sgl						
If Unit Dose, is item bar coded to	unit dose for	Country of Origin		Product Imprint:	19/74		Vial Liquid Sgi		If Voe how	many of wh	ich package	type?	
hospital scanning?	unit dose for	Is this product covered under	r the				Vial Powder Sql			Each	icii package	type:	
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?					Vial Power Multi			Inner/Cartor	n/Pack		
ii onit bose, indicate NBC here.							Other: Write In			Case	// ack		
		FOR GENERIC DRUG PRODUC	CTC				Other: White iii			Cuco			
		FOR GENERIC DRUG PRODUC	CIS										
Authorized Generic *If Authorized Generic, other							DU/	DMACY ODDED	/ DILL LIMIT				
	continuities are not				on fields are not applicable	PHARMACY ORDER / BILL UNIT							
		I. Orange Book Rating: AB			0001011 110100 010 1101 0pp 1100010		Rec. sell unit to customer?			Rx billing unit to pharmacy:			
II. Generic Equivalent to What Brand?:  Megace / N020264										Each			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION										Each			
			SA) INFORMATION			(Write-in, e.g. 1 Vial)				Gram			
			SA) INFORMATION			(Write-in, e.g. 1 Vial)							
Does supplier meet DSCSA defin	DRUC		SA) INFORMATION GLN:	0359556421464		(Write-in, e.g. 1 Vial)		AND PACKING IN		Gram Milliliter			
Does supplier meet DSCSA defin	DRUG	G SUPPLY CHAIN SECURITY ACT (DSCS		0359556421464		(Write-in, e.g. 1 Vial)		AND PACKING IN		Gram Milliliter			
Is product exempt from DSCSA?	DRUG	G SUPPLY CHAIN SECURITY ACT (DSCS	GLN:	0359556421464		(Write-in, e.g. 1 Vial)	ITEM		FORMATIO	Gram Milliliter	Volume	Saleable #	
Is product exempt from DSCSA?  If yes, select exemption:	DRUG	G SUPPLY CHAIN SECURITY ACT (DSCS		0359556421464		(Write-in, e.g. 1 Vial)		Dimensio	IFORMATION	Gram Milliliter		Saleable #	
Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in:	DRUG	G SUPPLY CHAIN SECURITY ACT (DSCS	GLN: GCP:			(Write-in, e.g. 1 Vial)	ITEM Weight Lbs.	Dimensio Depth	FORMATION ons (US msm Width	Gram Milliliter  N  Its.) Height	(Cube)		
Is product exempt from DSCSA?  If yes, select exemption:	DRUG	G SUPPLY CHAIN SECURITY ACT (DSCS	GLN: GCP: If yes, was or	0359556421464  original product lirect from mfr?			ITEM	Dimensio	IFORMATION	Gram Milliliter			
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged?	DRUG	Yes  No	GLN:  GCP:  If yes, was or purchased di	riginal product	ackaged product		Weight Lbs.	Dimension Depth 3.13	ons (US msm Width 5.55	Gram Milliliter	(Cube) 1.581	Pieces 1	
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	DRUC	Yes  No  No	GLN:  GCP:  If yes, was or purchased di	riginal product lirect from mfr?	ackaged product	Item/Each:	ITEM Weight Lbs.	Dimensio Depth	FORMATION ons (US msm Width	Gram Milliliter  N  Its.) Height	(Cube)		
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception	DRUC	Yes  No  No  No	GLN:  GCP:  If yes, was or purchased di Provide sour	riginal product lirect from mfr?	ackaged product	Item/Each: Box/Carton/Bundle/	Weight Lbs.  1.3  0	Dimension Depth 3.13	ons (US msm Width 5.55	Gram Milliliter  Nats.) Height 3.13	(Cube) 1.581 0	Pieces  1 0	
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