## HDA

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

						Introduction Ty	pe: New Item		x Final Version			Date:	02.12	2.2021
PRODUCT INFORMATION								SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Company Name: Strides Pharma Inc.							on: ANDA	a. Temperature – Indicate the USP temperature range f			or this product.			
Application Number for NDA/AN		MA/510(k)(med dev	/ice):	40:	350			Te	mperature Range	Controlled Room	– between 20	and 25 C (6	8° – 77° F)	
Medical Device Class, if applica														
DUNS:	11-8344-504							Oti	her Temperature Range F	Requirement	15° to 30°C	(59° to 86°F)		
Proprietary Name (If Applicable) a Selling Unit NDC:	64380-0212-02	ame: wethin	Unit of Use NDC:		1	UPC: 3	864380212027	- No	(write in) otes					
UDI	04300-0212-02		CVX Code:			MVX Code:	04300212027		1105					
Description:	White to off white	round flat-faced b	evelled-edged tablets, score	ed with "EM/5" c	on one side and				this product to be shipped	d to customers on i	ice?		No	1
Description.	white to on white	, round, nat raced, b	evened edged tablets, seere						this product to be shipped				No	
Active Ingredient(s):		Methimazole						-			, , , , , , , , , , , , , , , , , , ,		-	1
									mperature excursion qu	estions:				
URL for Additional Product Inforr Address:			d.nlm.nih.gov/dailymed	/drugInto.ctr	m?setid=ca8c	Address 2:	90df-b54818451bc3	Na	Michael Gargiulo 609-773-5004					
City:	1 Ram Ridge Rd Chestnut Ridge				State:		<b>Zip:</b> 10977		ımber: oup E-mail:		609-773-500	)4		
Key Contact:	Walt Busbee						rservice@stridesusa.com							
Phone Number:	609-773-5008							c. Special regula	tions for product in any	v states?			No	1
Product Therapeutic Classification:								Special returns requirements for this product? No						
					-			_						-
ADDITIONAL PRODUCT INFORMATION					PRODUCT DE	SCRIPTION INFORMATION	d. Store product	(unit of sale) upright?		No				
The product is?				Only				otect product (unit of sa	ale) from light?	No				
a legend device?		No	Is the Product	Neither		Size:	500	e. Shelf life:	tial abolf life at launab (	:f			36	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				5 mg		tial shelf life at launch (	if different):			24	Months
if yes, list NDCs of	FDA Approval Status Strength:									ORDER INFORM	ATION			
component parts						Dosage Form:	Tablets							
reverse numbered?		No				Dosage i onn.		Un	it of Sale		What is the		unit?	
co-licensed?		No	Allergens Present				David		X Bottle		1 Bottle of 5		0.)((.).)	
latex-free? preservative-free?						Product Shap	e: Round		Box/Carton Ampule		(write-in, e.	g. 1 Box of 1	0 viais)	
correctional institution block?		No					White to off-white		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No				Product Color	:		Tube			• •		
Cannabinoid?		No	Country of Origin	USA		Product Impri	EM;5		Vial Liquid Sgl					
If Unit Dose, is item bar coded to hospital scanning?	unit dose for		le this preduct sourced .	under the					Vial Liquid Multi		If Yes, how	-	ich package	type?
If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (		Yes				Vial Powder Sql Vial Power Multi		24	Each Inner/Cartor	Pack	
in onit bose, indicate NDO here.					103				Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS							1	1		
											4			
	No Authorized Generic *If Authorized Generic, other						If Authorized Generic, other section fields are not applicable	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating: AB						Rec. sell unit to customer?			Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: Methimazole														
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									1 Bottle		X	Each		
		Methimazole DRUG SUPPL	Y CHAIN SECURITY ACT (	DSCSA) INFO	RMATION			(Write-in, e.g. 1 V			X	Gram Milliliter		
		DRUG SUPPL	Y CHAIN SECURITY ACT (	(DSCSA) INFO	RMATION				/ial)			Gram Milliliter		
Does supplier meet DSCSA defin	nition of manufactu	DRUG SUPPL	Yes	(DSCSA) INFOI	RMATION GLN:	0359556421464			/ial)	AND PACKING IN		Gram Milliliter		
Is product exempt from DSCSA?	nition of manufactu	DRUG SUPPL		(DSCSA) INFO	GLN:	0359556421464			/ial)		IFORMATIO	Gram Milliliter N		
Is product exempt from DSCSA? If yes, select exemption:	nition of manufactu	DRUG SUPPL	Yes	(DSCSA) INFO		0359556421464			/ial)	Dimensio	IFORMATIO	Gram Milliliter N	Volume	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nition of manufactu	DRUG SUPPL	Yes No	(DSCSA) INFO	GLN: GCP:			(Write-in, e.g. 1 \	/ial) ITEM Weight Lbs.	Dimensio Depth	IFORMATIO ons (US msm Width	Gram Milliliter N nts.) Height	(Cube)	Saleable # Pieces
Is product exempt from DSCSA? If yes, select exemption:	nition of manufactu	DRUG SUPPL	Yes		GLN: GCP: If yes, was or	0359556421464			/ial) ITEM	Dimensio	IFORMATIO	Gram Milliliter N		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	nition of manufactu	DRUG SUPPL urer?	Yes No No		GLN: GCP: If yes, was or purchased di	riginal product irect from mfr?	repackaged product	(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund	/ial) ITEM Weight Lbs. 0.16	Dimensio Depth 2.04	IFORMATION ons (US msm Width 2.04	Gram Milliliter N hts.) Height 4.94	(Cube) 0.816	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer!	nition of manufactu s exclusive distrib on/exemption for p	DRUG SUPPL urer?	Yes No No No		GLN: GCP: If yes, was or purchased di	riginal product irect from mfr?	repackaged product	(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack:	/ial) ITEM Weight Lbs. 0.16	Dimensio Depth	IFORMATIO ons (US msm Width	Gram Milliliter N nts.) Height	(Cube)	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nition of manufactu s exclusive distrib on/exemption for p	DRUG SUPPL urer?	Yes No No No No		GLN: GCP: If yes, was or purchased di Provide sourc	riginal product irect from mfr?	repackaged product	(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund	/ial) ITEM Weight Lbs. 0.16	Dimensio Depth 2.04	IFORMATION ons (US msm Width 2.04	Gram Milliliter N hts.) Height 4.94	(Cube) 0.816	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nition of manufactu s exclusive distrib on/exemption for p	DRUG SUPPL urer?	Yes No No No		GLN: GCP: If yes, was or purchased di Provide sourc	riginal product irect from mfr?	repackaged product	(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack:	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23	Dimensio Depth 2.04 6.5 13.25	IFORMATION Dons (US msm Width 2.04 8.5 9	Gram Milliliter N Height 4.94 5.5 6	(Cube) 0.816 5 11.734	Pieces           1           12           24
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?	Yes No No No No		GLN: GCP: If yes, was or purchased di Provide sourc	riginal product irect from mfr?	repackaged product Unit of Use GTIN-14	(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case:	/ial) ITEM Weight Lbs. 0.16 dle/ 2	Dimension Depth 2.04 6.5	IFORMATION ons (US msm Width 2.04 8.5	Gram Milliliter N Height 4.94 5.5	(Cube) 0.816 5	Pieces           1           12
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?  Doutor? Droduct?  GTIR Galeable Quantity 1	Yes No No No No No		GLN: GCP: If yes, was or purchased di Provide source GTII 0036	riginal product irect from mfr? ce manufacturer for N-14 64380212027		(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet:	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23 452.24	Dimensio Depth 2.04 6.5 13.25	IFORMATION DIS (US msm Width 2.04 8.5 9 40	Gram Milliliter N Height 4.94 5.5 6 6 54	(Cube) 0.816 5 11.734 1700.352	Pieces           1           12           24           2112
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?  Doutor? Droduct?  GTI Saleable Quantity  1 12	Yes No No No No No		GLN: GCP: If yes, was or purchased di Provide source GTII 0036 2036	riginal product irect from mfr? ce manufacturer for N-14 64380212027 64380212021		(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet:	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23	Dimensio Depth 2.04 6.5 13.25	IFORMATION DIS (US msm Width 2.04 8.5 9 40	Gram Milliliter N Height 4.94 5.5 6 6 54	(Cube) 0.816 5 11.734	Pieces           1           12           24           2112
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack X Case	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?  Doutor? Droduct?  GTIR Galeable Quantity 1	Yes No No No No No		GLN: GCP: If yes, was or purchased di Provide source GTII 0036 2036	riginal product irect from mfr? ce manufacturer for N-14 64380212027		(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet:	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23 452.24	Dimensio Depth 2.04 6.5 13.25	IFORMATION Dons (US msm Width 2.04 8.5 9 40	Gram Milliliter N Height 4.94 5.5 6 6 54	(Cube) 0.816 5 11.734 1700.352	Pieces           1           12           24           2112
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?  Doutor? Droduct?  GTI Saleable Quantity  1 12	Yes No No No No No		GLN: GCP: If yes, was or purchased di Provide source GTII 0036 2036	riginal product irect from mfr? ce manufacturer for N-14 64380212027 64380212021		(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet:	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23 452.24 COST INFORMATION	Dimensio Depth 2.04 6.5 13.25 48	IFORMATION DIS (US msm Width 2.04 8.5 9 40	Gram Milliliter N Height 4.94 5.5 6 54 WHOLESALI	(Cube) 0.816 5 11.734 1700.352	Pieces           1           12           24           2112
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack X Case	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?  Doutor? Droduct?  GTI Saleable Quantity  1 12	Yes No No No No No		GLN: GCP: If yes, was or purchased di Provide source GTII 0036 2036	riginal product irect from mfr? ce manufacturer for N-14 64380212027 64380212021		(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23 452.24 COST INFORMATION	Dimensio Depth 2.04 6.5 13.25 48	IFORMATION ons (US msm Width 2.04 8.5 9 40 Vendor #:	Gram Milliliter N Height 4.94 5.5 6 54 WHOLESALL #:	(Cube) 0.816 5 11.734 1700.352	Pieces           1           12           24           2112
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack X Case	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?  Doutor? Droduct?  GTI Saleable Quantity  1 12	Yes No No No No No		GLN: GCP: If yes, was or purchased di Provide source GTII 0036 2036	riginal product irect from mfr? ce manufacturer for N-14 64380212027 64380212021		(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23 452.24 COST INFORMATION	Dimensio Depth 2.04 6.5 13.25 48	IFORMATIO ons (US msm Width 2.04 8.5 9 40 Vendor #: Whsl. Code	Gram Milliliter N Height 4.94 5.5 6 54 WHOLESALL #:	(Cube) 0.816 5 11.734 1700.352	Pieces           1           12           24           2112
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack X Case	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?  Doutor? Droduct?  GTI Saleable Quantity  1 12	Yes No No No No No		GLN: GCP: If yes, was or purchased di Provide source GTII 0036 2036	riginal product irect from mfr? ce manufacturer for N-14 64380212027 64380212021		(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WA	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23 452.24 COST INFORMATION	Dimensio Depth 2.04 6.5 13.25 48	IFORMATIO ons (US msm Width 2.04 8.5 9 40 Vendor #: Whsl. Code	Gram Milliliter N Height 4.94 5.5 6 54 WHOLESALL #:	(Cube) 0.816 5 11.734 1700.352	Pieces           1           12           24           2112
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack X Case	nition of manufactu 's exclusive distrib on/exemption for p om FDA.	DRUG SUPPL urer?  Doutor? Droduct?  GTI Saleable Quantity  1 12 24	Yes No No No No No No HIBCC PRODUCT IN HIBCC		GLN: GCP: If yes, was or purchased di Provide source 0036 2036 5036	riginal product irect from mfr? ce manufacturer for N-14 64380212027 64380212021 64380212022	Unit of Use GTIN-14	(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WA As of date:	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23 452.24 COST INFORMATION AC) (\$)	Dimensio Depth 2.04 6.5 13.25 48	IFORMATIO ons (US msm Width 2.04 8.5 9 40 Vendor #: Whsl. Code	Gram Milliliter N Height 4.94 5.5 6 54 WHOLESALL #:	(Cube) 0.816 5 11.734 1700.352	Pieces           1           12           24           2112
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack X Case	ition of manufactu 's exclusive distrib on/exemption for p om FDA. S	DRUG SUPPL urer?  Droduct?  GTI Saleable Quantity  1 2 4	Yes No No No No No No HIBCC PRODUCT IN HIBCC		GLN: GCP: If yes, was or purchased di Provide source 0036 2036 5036	riginal product irect from mfr? ce manufacturer for N-14 64380212027 64380212021 64380212022		(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Pallet: Regular Cost Invoice Cost (WA As of date:	/ial) ITEM Weight Lbs. 0.16 dle/ 2 4.23 452.24 COST INFORMATION AC) (\$)	Dimensio Depth 2.04 6.5 13.25 48	IFORMATIO ons (US msm Width 2.04 8.5 9 40 Vendor #: Whsl. Code	Gram Milliliter N Height 4.94 5.5 6 54 WHOLESALL #:	(Cube) 0.816 5 11.734 1700.352	Pieces           1           12           24           2112