



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

Version 2021

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Strides Pharma Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	40350
Medical Device Class, if applicable:	
DUNS:	11-8344-504
Proprietary Name (If Applicable) and Established Name:	Methimazole Tablets, USP
Selling Unit NDC:	64380-0212-01
Unit of Use NDC:	
UPC:	364380212010
UDI	
CVX Code:	
MX Code:	
Description:	White to off white, round, flat-faced, bevelled-edged tablets, scored with "EM/5" on one side and plain on the other.
Active Ingredient(s):	Methimazole
URL for Additional Product Information:	<a href="https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca8c1028-216d-485a-90df-b54818451bc3">https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca8c1028-216d-485a-90df-b54818451bc3</a>
Address:	1 Ram Ridge Rd
City:	Chestnut Ridge
State:	NY
Zip:	10977
Key Contact:	Walt Busbee
Email:	<a href="mailto:stridescustomerservice@stridesusa.com">stridescustomerservice@stridesusa.com</a>
Phone Number:	609-773-5008
Fax:	609-935-0806
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	<input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>
Other Temperature Range Requirement (write in)	<input type="text" value="15° to 30°C (59° to 86°F)"/>
Notes	
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text" value="Michael Gargiulo"/>
Number:	<input type="text" value="609-773-5004"/>
Group E-mail:	
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	<input type="text" value="No"/>
<b>Protect product (unit of sale) from light?</b>	<input type="text" value="No"/>
<b>e. Shelf life:</b>	<input type="text" value="36"/> Months
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product...	<input type="text" value="Direct-Ship Only"/>
a legend device?	<input type="text" value="No"/>	Is the Product...	<input type="text" value="Neither"/>
if yes, enter class #		Orphan Drug Status	
a product kit?	<input type="text" value="No"/>	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	
reverse numbered?	<input type="text" value="No"/>	Country of Origin	<input type="text" value="USA"/>
co-licensed?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="Yes"/>
latex-free?	<input type="text" value=""/>		
preservative-free?	<input type="text" value=""/>		
correctional institution block?	<input type="text" value="No"/>		
opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>		
If Unit Dose, indicate NDC here:			
Size:	<input type="text" value="100"/>	Strength:	<input type="text" value="5 mg"/>
Dosage Form:	<input type="text" value="Tablets"/>	Product Shape:	<input type="text" value="Round"/>
Product Color:	<input type="text" value="White to off-white"/>	Product Imprint:	<input type="text" value="EM;5"/>

ORDER INFORMATION	
Unit of Sale	<input checked="" type="checkbox"/> Bottle
	<input type="checkbox"/> Box/Carton
	<input type="checkbox"/> Ampule
	<input type="checkbox"/> Glass
	<input type="checkbox"/> Tube
	<input type="checkbox"/> Vial Liquid Sgl
	<input type="checkbox"/> Vial Liquid Multi
	<input type="checkbox"/> Vial Powder Sgl
	<input type="checkbox"/> Vial Powder Multi
	<input type="checkbox"/> Other: Write In
What is the NDC selling unit?	<input type="text" value="1 Bottle of 100 Tablets"/>
	(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity?	<input type="text" value="Yes"/>
If Yes, how many of which package type?	<input type="text" value="24"/> Each
	<input type="text" value=""/> Inner/Cartron/Pack
	<input type="text" value=""/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic
II. Generic Equivalent to What Brand?:	<input type="text" value="Methimazole"/>
*If Authorized Generic, other section fields are not applicable	

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	<input type="text" value="1 Bottle"/>
	(Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
If yes, attach documentation from FDA.	
GLN:	<input type="text" value="0359556421464"/>
GCP:	
If yes, was original product purchased direct from mfr?	<input type="text" value=""/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.07	2.04	2.04	3.3	0.364	1
Box/Cartron/Bundle/Inner Pack:	1	6.5	8.5	3.75	4	12
Case:	2.25	13.25	9	4.25	8.312	24
Pallet:	404	48	40	52	1637.376	3456

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each			00364380212010	
<input checked="" type="checkbox"/> Box/Cartron/Bundle/Inner Pack			20364380212014	
<input checked="" type="checkbox"/> Case			50364380212015	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	<input type="text" value="\$23.99"/>	Whsl. Code #:	
As of date:		Fineline Code:	

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

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: