

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

Version 2021						Introduction Type:	New Item		x Final Version			Date:	02.12	.2021
			PRODUCT INFORMA	TION					SPECIAL HAND	LING AND STOR	AGE REQUIR	REMENTS*		
							ANDA	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/A	NDA/BLA (drug); P	MA/510(k)(med o	device):	40350				Te	emperature Range	Controlled Room	– between 20	and 25 C (6	8° – 77° F)	
Medical Device Class, if applic	able:													
DUNS:	11-8344-504							Ot	her Temperature Range I	Requirement	15° to 30°C (59° to 86°F)		
Proprietary Name (If Applicable)		ame: Met	thimazole Tablets, USP						(write in)					
Selling Unit NDC:	64380-0213-01		Unit of Use NDC:	:			380213017	_ No	otes					
UDI			CVX Code:			MVX Code:								
Description:	white to off-white,	round, flat-faced,	bevelled-edged tablets, score	ed with "EM/10" on one si	de and p	plain on the other		Is	this product to be shipped	to customers on	ice?		No	
								Is	this product to be shipped	to customers on	dry ice?		No	
Active Ingredient(s):		Methimazole												
								b. Contact for te	mperature excursion qu	estions:				
URL for Additional Product Info		https://dailymed	l.nlm.nih.gov/dailymed/drugIn	fo.cfm?setid=0f5fb0a4-fe				- 1	ame:		Michael Garg			
Address:	1 Ram Ridge Rd				Address 2: tate: NY Zip: 10977				umber:		609-773-500	4		
City:	Chestnut Ridge							_ Gi	roup E-mail:					
Key Contact: Phone Number:	Walt Busbee 609-773-5008			Em Fa		<u>stridescustomerse</u> 609-935-0806	rvice@stridesusa.com	- Chaolal regula	stiana far praduat in any	ototoo?			No	1
				Га	Χ. [009-933-0000			ations for product in any				No	
Product Therapeutic Classificat	ion:							Sp	pecial returns requirement	s for this product?			No	l .
	ADDITIO	NAL BRODUCT	INFORMATION			PRODUCT DECC	PRINTION INFORMATION	.	/				NI.	I
	ADDITIO	DNAL PRODUCT	INFORMATION		_	PRODUCT DESC	RIPTION INFORMATION	⊣ ∣ '	(unit of sale) upright?				No	Į.
The product is?			Is the Product	Direct-Ship Only	. I				otect product (unit of sa	le) from light?			No	1
a legend device?		No	Is the Product	Neither	_	Size:	100	e. Shelf life:					36	Months
if yes, enter class #			Orphan Drug Status				10	In	itial shelf life at launch (f different):			24	Months
a product kit?		No	EDA Amananal Ctatus			Strength:	10 mg			OPPER INCORN	ATION			
if yes, list NDCs of component parts			FDA Approval Status				Tablets			ORDER INFORM	IATION			
reverse numbered?		No				Dosage Form:	Tablets	,,	nit of Sale		What is the l	NDC selling	ı unit?	
co-licensed?		No	Allergens Present					'II <u>ë</u>	X Bottle		1 Bottle of 10		, unit:	
latex-free?		110	Allergens i resem				Round		Box/Carton		(Write-in, e.g		0 Vials)	
preservative-free?						Product Shape:			Ampule		(**************************************	,	,	
correctional institution block	?	No			_	December Colons	White to off-white		Glass		Minimum or	der quantity	y?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	"EM/10" on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	o unit dose for					i roduct imprint.	plain on the other		Vial Liquid Multi		If Yes, how I	many of wh	ich package	type?
hospital scanning?			Is this product covered		_				Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)? Yes					Vial Power Multi			Inner/Cartor	n/Pack	
								<u> </u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	RODUCTS										
	No. A start of Occasion Att Authorized Consein attention							DUARMA OV ORDER (DUA LINUT						
				No	No Authorized Generic *If Authorized Generic, other section fields are not applicable			PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB					360	lion helds are not applicable	Rec. sell unit to			Rx billing ur	-	асу:	
II. Generic Equivalent to What Brand?: Methimazole							1 Bottle			x Each				
		DDUG GUD	DLY QUAIN OF QUIDITY ACT	(DOOGA) INFORMATIO				(Write-in, e.g. 1	√ial)			Gram		
		DRUG SUP	PLY CHAIN SECURITY ACT	(DSCSA) INFORMATIO	N .							Milliliter		
Does supplier meet DSCSA defi	inition of manufactu	ıror?	Yes	GLN:	(0359556421464			ITEM	AND PACKING II	NEORMATION	J		
Is product exempt from DSCSA'		161:	No	- OLN.		0000000421404			II EM	AND I AGINING II	II OKIMATION	•		
•	•		110							5	(110	(- X	V-1	0-111-
If yes, select exemption:				GCP:					Weight Lbs.		ons (US msm	-		Saleable Pieces
Other exemption - Write in: Is product repackaged?			No	If you	vas origi	inal product		Item/Each:		Depth	Width	Height	(Cube)	rieces
Is product repackaged? Is product sold by manufacturer	r's pyclusive distrib	utor?	No		_	ct from mfr?			0.09	2.04	3.3	2.04	0.364	1
Has FDA granted waiver/except			No			manufacturer for re	packaged product	Box/Carton/Bun	dle/					
If yes, attach documentation fr				1100100	254.00		product	Inner Pack:	1.1	6.5	3.75	8.5	4	12
, ,								Case:	0.00	40.05	4.05		2.242	0.4
		<u>_</u>	TIN AND HIBCC PRODUCT I	NFORMATION					2.66	13.25	4.25	9	8.312	24
								Pallet:	463.04	10	50	40	1627 276	2/50
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTIN-	14	Unit of Use GTIN-14	.	403.04	48	52	40	1637.376	3456
x Item/Each						380213017								
x Box/Carton/Bundle/Inner Pack	(380213011			COST INFORMATION		V	HOLESAL	ER USE ONL	Y:
x Case					503643	380213012								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (W	AC) (\$)	\$41.43	Whsl. Code			
								1	0/4.4/0000		Fineline Cod	ie:		
								As of date:	3/14/2022		-			
								П						
<u> </u>			A 1	TA OUEET (02.5)			-DT ADE: AND	<u> </u>	UNIO 15:50555		<u> </u>			
*Please provide any additional i	land a managed to the		Attach copy of SAFETY DA	IA SHEET (SDS) or non			ERT, LABEL AND PHOTO OF ignated Drop Ship Only.		SING and BARCODE.					