

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

Second Second Color Second Colo	Version 2021						Introduction Type:	New Item		x	Final Version			Date:	17.06	6.2024	
The product of Shape Control of Shape				PRODUCT INFORMAT	TON						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*			
Application	Company Name: Strides Pharma Inc. Application: Application: Application									a. Temperature – Indicate the USP temperature range for this product.							
Microse Content Experiment Content Experiment Content				ice):	20	2330											
State			,											· · ·			
Page of the present	DUNS:	91-85-13263				1			1	Other Ter	nperature Range	Requirement					
Comparison Com	Proprietary Name (If Applicable) a	and Established Na	ame: Buspir	one Hydrochloride tablets U	SP [15mg][180's	s][VA]						•					
Description: Section of a label well-updated colored and place of a label well-updated and place all and place of a label well-updated and place all and	Selling Unit NDC:	42543-0743-18		Unit of Use NDC:			UPC: 3425	43743182		Notes							
Since state Topic register Topic r	UDI			CVX Code:			MVX Code:										
Since state Topic register Topic r	Description:	White to off white	rectangular uncoated	d tablet with bisected score I		Is this pro	duct to be shippe	d to customers on	ce?		No	1					
Control Cont	•								1								
Manufaces	Active Ingredient(s): Buspirone Hydrochloride Tablets, USP 15 mg															-	
Address: Sear Right Bell Sea Right Bell		b. Contact for	r temperati	ure excursion qu	estions:												
City: Command Roger																	
Final Product Control (2005) 19 (200			5							_		609-770-5004					
Pione Number: BEST75-0073 by BEST75-		Chestnut Ridge							Group E-	mail:							
Special files for the product		600 772 5009						- Cunnini nam	latlana fa		1-12				n .		
ABORTOWAL PRODUCT NOOMATION The product is? In the Product As agained elevior? No. 1 but Product. Opinion Dispose Notice of Composers of the Product Notice of Composers of Comp						гах.	609-935-0806									A	
Be granded kill of the formation of such product (unit of sale) Prod	Product Therapeutic Classificatio	on:								Special re	eturns requiremen	its for this product?				4	
Be granded kill of the formation of such product (unit of sale) Prod		ADDITIO	ONAL PRODUCTINI	FORMATION			BRODUCT DESCE	DIRTION INFORMATION	4 640-0 0-0-4		f aala\					п	
a larged devices? No. Sheet Mile. Size: Size:		ADDITIO	SNAL PRODUCT IN				FRODUCT DESCR	IFTION INFORMATION	a. Store produ							4	
See: ## 1805 of James Toward Control See: ## 1805 See: ## 1805	·					Only				Protect p	roduct (unit of s	ale) from light?				4	
Post			No		Neither		Size:	180's	e. Shelf life:						36	-	
If yes, select exemption: Post Approval Status	1 1			Orphan Drug Status						Initial she	elf life at launch	(if different):				Months	
Composite parts reverse numbere? No Allergens Present Liller-Chee? No Allergens Present Product Shape: Product Color: Product Imprint: Description of Sale What is the NDC selling unit? (Witten A., e., 15 to. of 10 Viria) Minimum order quantity? Vision Minimum order quantity? Vision Well Lipid Multis Product Color: Product Imprint: Description of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the color of the part search of some lines; on the part search of the part search of some lines; on the part search				FDA Ammerical Status				OPDER INFORM	MATION								
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Lo-discretified 1 to be product Shape: Product Shape:			No				Dosage Form:	Tablets		Unit of S	ale		What is the	NDC selling	unit?		
Inter-chere? preservative-free? correctional institution block? copilable? Country of Origin India product Color- glober? Country of Origin India product Shape: Product Color- product Imprint: Since For Selectic Color- product Selectic Selectic Selectic Color- product Selectic				Allergens Present											,		
presentative-free? correctional institution block? Country of Origin India Product Color: Product Color: Product Color: Product Marpinit Season Seaso				g									(Write-in, e	g. 1 Box of 1	0 Vials)		
opiol? Canabinoid? If Unit Dose, is letin but coded to unit dose for hospital scanning. If Unit Dose, indicate NDC here: If unit Dose, interest, in unit Unit Unit Unit Unit Unit Unit Unit U	preservative-free?						Product Shape:	rectangular		-							
General Country of Origin India Froduct Imprint: Diseases here bar cooled to unit does for If Unit Dase, indicate NDC here: If Authorized Generic, other section fields are not applicable Section Fields are not applicable If Authorized Generic, other section fields are not applicable If Authorized Generic, other section fields are not applicable If yes, select exempt from DSCSA definition of manufacturer? Yes GLN:	correctional institution block?						Product Color:	white to off white			Glass		Minimum o	rder quantit	y?	Yes	
From the rocked to unit dose for less and freework From the possible seaming? If Unit Dose, Indicate NDC here: Trade Agreements Act (TAA)? No	opioid?						Froduct Color.	write to oil write			Tube						
Fund Dose, indicate NDC here: Is this product covered under the Track Agreements Act (TAA)? No No Authorized Generic, other section fields are not applicable. No Authorized Generic, other section fields are not applicable. No Authorized Generic, other section fields are not applicable. No Authorized Generic, other section fields are not applicable. No Authorized Generic, other section fields are not applicable. No Authorized Generic, other section fields are not applicable. No Authorized Generic, other section fields are not applicable. No Generic Equivalent to What Brand?: BUSPAR / 018731 No Generic Equivalent to What Brand?: Busiley No Generic Equivalent to What Brand?: Busiley No Generic Generic, other secreption. Generic Equivalent to What Brand? No Generic Generic Generic, other secreption. Generic Equivalent to What Brand?: Busiley No Generic Generic Generic Generic, other secreption. Generic Generi	Cannabinoid?			Country of Origin	India		Product Imprint:	hisected score lines on			Vial Liquid Sgl						
Trade Agreements Act (TAA)? No		unit dose for					i roddot iii.priiiti						If Yes, how	-	ich package	type?	
Corange Book Rating: Rec. self unit to customer? Rec. self u	1 1 -																
I. Corange Book Rating: II. Generic Equivalent to What Brand?: BUSPAR / 018731	If Unit Dose, indicate NDC here:		-					n/Pack									
NO Authorized Generic, other section fields are not applicable South Frank Suspension											Other: Write In		1	Case			
Coarge Book Rating: AB				FOR GENERIC DRUG PRO	DDUCTS					Į.							
Coarge Book Rating: AB						NO A	therized Constine #16 A.	therinad Canaria ather			DU	ADMACY ORDER	/ DILL LINIT				
Generic Equivalent to What Brand?: BUSPAR / 018731	section fields are not applicable																
Case			I			Coolin Holde are not applicable			Rec. sell unit		er?	7					
Does supplier meet DSCSA definition of manufacturer? Yes GLN:	II. Generic Equivalent to What Bra	and?:	BUSPAR / 018731										Х	!			
Saleable Unit of Measure Saleable Quantity	DDIJC SUBDI V CHAIN SECURITY ACT (DSCSA) INFORMATION																
Seproduct exempt from DSCSA? No GCP:			DRUG SUITE	T CHAIN SECONTT ACT (JOCOA) IN ON	MATION								willille			
Seproduct exempt from DSCSA? No GCP:	Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:					ITEM	I AND PACKING I	NFORMATIO				
First Select exemption: Other exemption: Ot						J											
Saleable Unit of Measure Saleable Quantity Total Residence	If yes select exemption:					GCP:			i			Dimensi	ons (US msr	nts.)	Volume	Salaabla#	
Seproduct repackaged? No If yes, was original product Seproduct solid by manufacturer's exclusive distributor? No No Provide source manufacturer for repackaged product No P						JUI .			1		Weight Lbs.		-	-			
Sproduct sold by manufacturer's exclusive distributor? No Purchased direct from mfr? Provide source manufacturer for repackaged product Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Vanish Regular Cost Invoice Cost (WAC) (\$) Whole Code #: Fineline Code: Fineline Co				No		If ves, was or	riginal product		Item/Each:								
Has FDA granted waiver/exception/exemption for product? No Provide source manufacturer for repackaged product		s exclusive distrib	utor?								0.177	1.890	1.890	3.740	13.360	1	
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Example Management								ackaged product	Box/Carton/B	undle/	2.250	7 002	6.024	4 OEE	105 222	12	
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14	If yes, attach documentation fro	m FDA.			_				Inner Pack:		2.350	7.992	6.024	4.055	195.223	12	
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Saleable Quantity HIBCC GT									Case:		11.855	14 567	10 433	11 220	1705 188	48	
Saleable Unit of Measure X			GTIN	I AND HIBCC PRODUCT IN	IFORMATION							1 1.007	10.100		1700.100	.0	
Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Unit of Use GTIN-14 Un	II								Pallet:		435.303	48	40	38.898	74684.160	1584	
X Sox/Carton/Bundle/Inner Pack 12 20342543743186 50342543743186 50342543743187 70342543743181 Regular Cost (WAC) (\$) Whsl. Code #:		S		HIBCC				Unit of Use GTIN-14							50		
X Case 48 50342543743187 Regular Cost Whole Cost (WAC) (\$) Whist. Code #: Fineline Code:	 								COST INFORMATION WHOLESALED USE ONLY								
X Pallet 1,584 70342543743181 Regular Cost Whole (WAC) (\$) Whist. Code #:										CUSI	INFORMATION			VIOLESAL	ER USE UNI	518	
Invoice Cost (WAC) (\$) Whsl. Code #: Fineline Code: As of date:									Regular Cost				Vendor #				
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As of date:			1,364														
			1,564						mivoice oost ((
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.			1,364							(e, (¢,							
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.			1,384				_			[
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