

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

Version 2021							Introduction 7	Туре:	New Item		x	Final Version			Date:	17.10	.2022
				PRODUCT INFORMAT	ION							SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Strides Pharma, Inc. ANDA a						a. Temperature – Indicate the USP temperature range for this product.											
Application Number for NDA/AN	IDA/BLA (drug); P	MA/510(k)(m	ed device	e):	207	7029						ure Range	Controlled Room	-		8° – 77° F)	
Medical Device Class, if applicat	ble:																
	91-851-3263										Other Ter	nperature Range I	Requirement				
Proprietary Name (If Applicable) a		ame:	Hydroco	rtisone Tablets 20mg, 100	ct	1						te in)					
0	64380-0972-06			Unit of Use NDC:			UPC:	36438097	72068		Notes						
UDI				CVX Code:			MVX Code:										
Description:	White to off-white	oval tablets d	lebossed	on one side with a bisect a	and other side w	/ith "H20"					-		d to customers on i			No	
Is this product to be shipped to customers on dry ice? No																	
Active Ingredient(s): Hydrocortisone Tablets, USP 20 mg b. Contact for temperature excursion questions:																	
URL for Additional Product Inform	mation:									b. contact for	Name:	ure excursion qu	6310113.	Michael Gar	aiulo		
Address:	1 Ram Ridge Rd.	l					Address 2:				Number:			609-773-500			
City:	Chestnut Ridge				NY	Zip: 1	10977		Group E-	mail:							
Key Contact:	Walt Busbee					nerservice	e@stridesusa.com										
Phone Number:	609-773-5008	Fax: 609-935			609-935-0806			c. Special regulations for product in any states?									
Product Therapeutic Classification: Special returns requirements for this product?																	
		ONAL PRODU					PRODUCT	DESCRIPT	TION INFORMATION	d Store wood		(colo) unviento					
	ADDITIC						PRODUCTI	DESCRIPT	ION INFORMATION	a. Store prod		f sale) upright?					
The product is?			1	Is the Product	Direct-Ship C	Dnly		_			Protect p	roduct (unit of sa	ale) from light?			0.4	
a legend device? if yes, enter class #		No		Is the Product Orphan Drug Status	Neither		Size:	10	00	e. Shelf life:	Initial ch	elf life at launch (if different).			24	Months Months
a product kit?				Orphan Drug Status						1	initial Sile	en me at launen (il different).				WOITINS
if yes, list NDCs of			1	FDA Approval Status			Strength:	20) mg				ORDER INFORM				
component parts							Dosage For	rm: To	ablets								
reverse numbered?		No					Dosage For				Unit of S			What is the		y unit?	
co-licensed?		No		Allergens Present				_		-		Bottle		Bottle x 100			
latex-free?							Product Sha	ape: ov	val tablets			Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?								-		4		Ampule Glass		Minimum o	rdar quantit	~ ~	Yes
opioid?							Product Col	olor: W	hite to off-white			Tube		winimum o	rder quantit	y f	res
Cannabinoid?				Country of Origin	India					1		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		1	, ,			Product Imp		bisect and other side with			Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?				Is this product covered un						1		Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:				Trade Agreements Act (T	AA)?	No						Vial Power Multi			Inner/Cartor	/Pack	
												Other: Write In		1	Case		
			F	OR GENERIC DRUG PRO	DUCTS												
						NO Au	thorized Generic	*If Author	rized Generic, other			PH/	ARMACY ORDER				
					-	NO Au	unonzeu Generic		elds are not applicable	Dee cellumit	4.0						
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB		Dharmac	ia and Upjohn) N008697						Rec. sell unit	Bottle	er :	1	Rx billing u	Each	lacy:	
II. Generic Equivalent to what bia		CONTLI	Filailliac							(Write-in, e.g.			1	X	Gram		
		DRUG S	SUPPLY (CHAIN SECURITY ACT (D	SCSA) INFOR	MATION				(********, **)	,				Milliliter		
					_									<u>.</u>			
Does supplier meet DSCSA defini	ition of manufactu	urer?		Yes	_	GLN:						ITEM	AND PACKING IN	IFORMATION	N		
Is product exempt from DSCSA?				No													
If yes, select exemption:						GCP:						Weight Lbs.		ons (US msn			Saleable #
Other exemption - Write in:				Na		16				literry / Teach			Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	s ovclusivo distrib	utor?		No	-	•	riginal product rect from mfr?			Item/Each:		0.093901	1.772	1.772	3.504	11.002504	1
Has FDA granted waiver/exceptio			<u> </u>	No	-	•	ce manufacturer f	for repack	aged product	Box/Carton/B	undle/						
If yes, attach documentation fro									-g p	Inner Pack:		NA	NA	NA	NA	NA	NA
										Case:		9.275778	14.764	9.252	7.874	1075.5611	80
			GTIN A	ND HIBCC PRODUCT IN	FORMATION							5.215110	14.704	3.2.32	7.074	1010.0011	00
	-			1000		0.71				Pallet:		489.3273	47.992	39.09	40	75040.291	3840
Saleable Unit of Measure	S	Saleable Quan	uty 1	HIBCC		-	N-14 64380972068	_ (Unit of Use GTIN-14								
X Item/Each Box/Carton/Bundle/Inner Pack		NA	1			NA	04300972000	- L			COST	INFORMATION			NHOLESAL	ER USE ONL	٧.
X Case		80	1				64380972063	-				In on one					
X Pallet		3840	1				64380972067			Regular Cost				Vendor #:			
										Invoice Cost	(WAC) (\$)		\$154.20	Whsl. Code			
											,			Fineline Co	de:		
	-							_		As of date:							
ļ			٨٠	ach conv of SAEETV DAT) or non hozor	d latter DACKAGE		LABEL AND PHOTO OF P					ļ			
*Please provide any additional inf	ormation on nage	2.	All	acticopy of SAPETT DAT.		or non nazar	-	-	ted Drop Ship Only.	NODUCI FACK	Signature						
	en page							soignat			gnatal						

HDA

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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3							
MATERIAL HAZA	RD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning?	SDS Hazard Classification Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? Is this product regulated for shipment by DOT?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	If yes, indicate which: Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
a. Orviderinitiation Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:						
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:	Phone: DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry:	Dhanay					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Comments	Phone:					
Is the Product Controlled Substance? Controlled Substance? Controlled Substance Code Controlled by State(s)? Listed Chemical (List I or II) ARCOS Reportable? If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?:	RETUR Contact tel. # if product received damaged: Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
	Polooso DATE						



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Version 2021	FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	not a designated drop ship, do not complete.
Order Method	I for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #:	Fax Number: Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
	Phone:	
Expedited Freight Ch	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each ord Drop Ship service fee billed with each ord Drop Ship miscellaneous fees billed: Comments:		Overnight receipt available: Monday PO Receipt cut off time: Monday Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday Priority Operminist receipt available: Friday
	ener of Tanala Descriptions	Priority Overnight receipt available:
		PO Receipt Cut off time: PO Receipt Cut off time: PO Receipt Cut off time: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Image: Content of the tee section of the tee section of tee section
Other Data Ir	formation Required to Process PO:	Return Instructions
Patient Procedure Date:Physician Name:Physician/Clinic Phone #Physician State License #Physician/Clinic DEA #:Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
	Miscellaneous Notes:	
		ADDITIONAL INFORMATION Is product order for scheduled patient procedure?
		Is product order for restocking purposes?