

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

				Introduction Type:	New Item] [x Final Version			Date:	9/1/2	2021	
		PRODUCT INFORMATION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*			
Company Name:				Application:	ANDA	a. Temperature – Indicate the USP temperature range for t							
Application Number for NDA/AN	NDA/BLA (drug); PMA/510(k)(med device): ANDA209597						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS:	963322560					Ott	ner Temperature Range F	Requirement					
Proprietary Name (If Applicable) a		styramine for Oral Suspension USP, Po	wder			<u> </u>	(write in)						
Selling Unit NDC:	51224-0011-20	Unit of Use NDC: CVX Code:		UPC: MVX Code:		- No	tes						
02.				WVX Code.					_				
Description:	Cholestyramine, USP 4g Pouch 60CT						this product to be shipped this product to be shipped				No No		
Active Ingredient(s):	Cholestyramine						ins product to be snipped	to customers on c	ily ice:	-	140		
3 ,						b. Contact for ter	nperature excursion qu	estions:					
URL for Additional Product Inform		<u>na.com</u>					me:		Kevin Becker				
Address: City:	722 Progressive Lane South Beloit		State:	Address 2: Room	205 61080		mber: oup E-mail:		815-624-768	tagipharma	com		
Key Contact:	Drake Sundstrom		Email:	dsundstrom@tagip		-	oup E-mail.		urugiiilo@	Lagipilarilla	i.COIII		
Phone Number:	815-624-7685		Fax:	815-624-4628	<u> </u>	c. Special regulat	ions for product in any	states?			No		
Product Therapeutic Classificatio	on:					Sp	ecial returns requirement	s for this product?		-	No		
	<u> </u>					_				-			
	ADDITIONAL PRODUCT IN	FORMATION		PRODUCT DESC	RIPTION INFORMATION	d. Store product	(unit of sale) upright?				Yes		
The product is?			and Drop-Ship				otect product (unit of sa	ile) from light?			No	ì	
a legend device?	No	Is the Product Neither	_	Size:		e. Shelf life:	(- - -	£ -1166			36	Months	
if yes, enter class # a product kit?	No	Orphan Drug Status			4g	ini'	tial shelf life at launch (t different):				Months	
if yes, list NDCs of	140	FDA Approval Status		Strength:	79			ORDER INFOR	MATION				
component parts				Dosage Form:	Powder								
reverse numbered?	No			Dosage i oi iii.		Un	it of Sale			NDC selling	unit?		
co-licensed? latex-free?	Yes	Allergens Present			N.A		Bottle x Box/Carton		1 carton of 6	0 pouches g. 1 Box of 10) //iolo)		
preservative-free?				Product Shape:	N.A		Ampule		(vviite-iii, e.i	g. 1 BOX 01 10	viais)		
correctional institution block?				Product Color:	Yellow (Pale Yellow)		Glass		Minimum or	der quantity	?	Yes	
opioid?	No			Product Color:			Tube				•		
Cannabinoid?	No No	Country of Origin Spain		Product Imprint:	None		Vial Liquid Sgl					_	
If Unit Dose, is item bar coded to uscanning?	unit dose for hospital	Is this product covered under the					Vial Liquid Multi Vial Powder Sql		If Yes, how	many of whice Each	:h package t	ype?	
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	Yes				Vial Power Multi			Inner/Carton/	/Pack		
		,					Other: Write In		1	Case			
		FOR GENERIC DRUG PRODUCTS							1				
							-						
			Autho		norized Generic, other section			ARMACY ORDER					
			I. Orange Book Rating: AB fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:							
ii. Generic Equivalent to what Bra	II. Generic Equivalent to What Brand?: Prevalite					1 Teo. Sen unit to c				(Write-in e.g. 1 Vial)			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								l		Gram			
	DRUG SUPPL	LY CHAIN SECURITY ACT (DSCSA) II	NFORMATION			(Write-in, e.g. 1 V				Gram Milliliter			
							ial)			Milliliter			
Does supplier meet DSCSA defini	ition of manufacturer?	Yes	NFORMATION GLN:	GLN 0351224000001			ial)	AND PACKING I	NFORMATION	Milliliter			
Is product exempt from DSCSA?	ition of manufacturer?			GLN 0351224000001			ial)			Milliliter N	Valuma		
Is product exempt from DSCSA? If yes, select exemption:	ition of manufacturer?	Yes		GLN 0351224000001	1		ial)	Dimens	ions (US msm	Milliliter	Volume (Cube)	# Pieces:	
Is product exempt from DSCSA?	ition of manufacturer?	Yes	GLN:	GLN 0351224000001			ial)			Milliliter N	Volume (Cube)	# Pieces:	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor?	Yes No Yes	GLN: If Yes, was origin direct from mfr?	nal product purchased		(Write-in, e.g. 1 V	ITEN Weight Lbs.	Dimens	ions (US msm	Milliliter		# Pieces:	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	s exclusive distributor?	Yes No	GLN: If Yes, was origin direct from mfr?	nal product purchased		(Write-in, e.g. 1 V	ITEN Weight Lbs.	Dimens	ions (US msm	Milliliter		# Pieces:	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor?	Yes No No Yes No	GLN: If Yes, was origing direct from mfr? If yes, attach door	nal product purchased		(Write-in, e.g. 1 V	Weight Lbs.	Dimensi Depth 4.92	ions (US msm Width	Milliliter N hts.) Height 5.71		1	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor?	Yes No Yes	GLN: If Yes, was origing direct from mfr? If yes, attach door	nal product purchased		(Write-in, e.g. 1 V	ITEN Weight Lbs.	Dimens Depth	ions (US msm Width	Milliliter N nts.) Height			
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor?	Yes No No Yes No	GLN: If Yes, was origing direct from mfr? If yes, attach door	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 V	Weight Lbs.	Dimensi Depth 4.92	ions (US msm Width	Milliliter N hts.) Height 5.71		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/exceptio	s exclusive distributor? on/exemption for product?	Yes No No Yes No No IN AND HIBCC PRODUCT INFORMAT	If Yes, was origin direct from mfr? If yes, attach doo TION	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 V Item/Each: Box/Carton/Bund Inner Pack: Case:	Weight Lbs.	Dimensi Depth 4.92	ions (US msm Width	Milliliter N hts.) Height 5.71		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/exceptio Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack	s exclusive distributor? n/exemption for product? Quantity	Yes No No Yes No No IN AND HIBCC PRODUCT INFORMAT	If Yes, was origing direct from mfr? If yes, attach document of the control of th	nal product purchased cumentation from FDA.	Unit of Use GTIN-14		Weight Lbs. 1.23 15.59	Dimensi Depth 4.92	5.12 12.36	Milliliter Nts.) Height 5.71 10.79	(Cube)	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/exceptio	s exclusive distributor? on/exemption for product?	Yes No No Yes No No IN AND HIBCC PRODUCT INFORMAT	If Yes, was origing direct from mfr? If yes, attach document of the control of th	nal product purchased cumentation from FDA.	Unit of Use GTIN-14		Weight Lbs.	Dimensi Depth 4.92	5.12 12.36	Milliliter N hts.) Height 5.71	(Cube)	1 12	
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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/exceptio Saleable Unit of Measure hem/Each Bow/Carton/Bundle/Inner Pack Case	s exclusive distributor? n/exemption for product? Quantity	Yes No No Yes No No IN AND HIBCC PRODUCT INFORMAT	If Yes, was origing direct from mfr? If yes, attach document of the control of th	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 V Item/Each: Box/Carton/Bunclinner Pack: Case: Pallet:	Weight Lbs. ILLEY 1.23 15.59 COST INFORMATION	Dimensi Depth 4.92 16.69	ions (US msm Width 5.12 12.36 Vendor #: Whsl. Code	Milliliter N hts.) Height 5.71 10.79 WHOLESALE #:	(Cube)	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/exceptio Saleable Unit of Measure hem/Each Bow/Carton/Bundle/Inner Pack Case	s exclusive distributor? n/exemption for product? Quantity	Yes No No Yes No No IN AND HIBCC PRODUCT INFORMAT	If Yes, was origing direct from mfr? If yes, attach document of the control of th	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost (WA	Weight Lbs. ILLEY 1.23 15.59 COST INFORMATION CC) (\$)	Dimensi Depth 4.92 16.69	ions (US msm Width 5.12 12.36 Vendor #:	Milliliter N hts.) Height 5.71 10.79 WHOLESALE #:	(Cube)	1 12	
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD 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?	Organic Corrosive Inorganic Oxidizer					
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?	Is the product a NIOSH hazardous drug? If yes, indicate which:					
(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? Ye	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 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 Is this a reportable quantity? No	Limited Distribution Requirement Comments / Details: (For example, iPledge program?) REMS:					
RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: Comments Phone: Phone: DEA #: PCPDP#: NPI #:					
SP# ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments Phone:					
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 800-397-9228					
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? Yes					
MISCELL	ANEOUS NOTES and/or Image of Product Barcode:					



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

Version 2020

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing				
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier				
a. EDI		Cut off time: Central				
b. Autofax	Fax Number:					
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days				
d. Phone only	Phone No.:					
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:				
Minimum Order Quantity:		Ships for second day receipt:				
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:				
Contracted 3PL company / contact #:	Name:					
	Phone:					
Expedited Freight Ch	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each ord	<u></u>	Overnight receipt available:				
Drop Ship service fee billed with each ord	er:	PO Receipt cut off time:				
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday				
Comments:		Tuesday				
		Wednesday				
		Thursday				
		Friday				
		Priority Overnight receipt available:				
CI	ass of Trade Restriction:	PO Receipt Cut off time:				
No restriction: Select YES if sold to retail a	oharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:				
Restricted to retail pharmacy only:		PO Receipt Cut off time:				
Restricted to hospital, clinics, and physicia	an offices only:	Phone: Phone #:				
Restricted from US territories? (explain in	comments)	Order receipt method: Fax: Fax #:				
Comments:		EDI:				
		Overnight Fees apply:				
		Other fees apply:				
Other Data Ir	nformation Required to Process PO:	Return Instructions				
Patient Procedure Date:		Contact # if product is received damaged:				
Physician Name:		Is product returnable for credit:	_			
Physician/Clinic Phone #		URL/Link to returns policy:				
Physician State License #						
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?				
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?				
	Miscellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure?				
		Is product order for restocking purposes?				
		to product crack for restocking purposes:				