



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

Version 2020

Introduction Type:  New Item

Final Version

Date: 9/1/2021

PRODUCT INFORMATION				
Company Name:	TAGI Pharma Inc.		Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	ANDA209597			
DUNS:	963322560			
Proprietary Name (if Applicable) and Established Name:	Cholestyramine for Oral Suspension USP, Powder			
Selling Unit NDC:	51224-0011-20	Unit of Use NDC:	UPC:	
UDI		CVX Code:	MXV Code:	
Description:	Cholestyramine, USP 4g Pouch 60CT			
Active Ingredient(s):	Cholestyramine			
URL for Additional Product Information:	<a href="http://www.tagipharma.com">www.tagipharma.com</a>			
Address:	722 Progressive Lane	Address 2:	Room 205	
City:	South Beloit	State:	IL	
Key Contact:	Drake Sundstrom	Zip:	61080	
Phone Number:	815-624-7685	Email:	<a href="mailto:dsundstrom@tagipharma.com">dsundstrom@tagipharma.com</a>	
		Fax:	815-624-4628	
Product Therapeutic Classification:				

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
<b>b. Contact for temperature excursion questions:</b>	
Name:	Kevin Beckett
Number:	815-624-7685
Group E-mail:	<a href="mailto:druginfo@tagipharma.com">druginfo@tagipharma.com</a>
<b>c. Special regulations for product in any states?</b>	No
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	Yes
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	36 Months
Initial shelf life at launch (if different):	Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	No	Is the Product... Direct And Drop-Ship	
if yes, list NDCs of component parts	No	Is the Product... Orphan Drug Status	Neither
reverse numbered?	No	FDA Approval Status	
co-licensed?	Yes	Allergens Present	
latex-free?		Country of Origin	Spain
preservative-free?		Is this product covered under the Trade Agreements Act (TAA)?	Yes
correctional institution block?			
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			
		Size:	
		Strength:	4g
		Dosage Form:	Powder
		Product Shape:	N.A
		Product Color:	Yellow (Pale Yellow)
		Product Imprint:	None

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 carton of 60 pouches
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	Each
<input type="checkbox"/> Vial Power Multi	Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	1 Case

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	Each
	Gram
	Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	GLN: GLN 0351224000001
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	Yes
Has FDA granted waiver/exception/exemption for product?	No
	If Yes, was original product purchased direct from mfr? If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Depth	Width	Height	Volume (Cube)	# Pieces:
Box/Carton/Bundle/Inner Pack:	1.23	4.92	5.12	5.71		1
Case:	15.59	16.69	12.36	10.79		12
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each				
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	1		00351224011205	
<input checked="" type="checkbox"/> Case	12		50351224011200	
Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$111.15	Whsl. Code #:	
As of date:	9/10/2021	Fine Line Code:	



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For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?  No
  - b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
    - Is the product a CA Prop 65 carcinogen?  No
    - Is the product a CA Prop 65 reproductive toxicant?  No
    - Does the product label bear a CA Prop 65 warning?  No
  - c. Contact Hazard?  Yes
  - d. Does this product require special clean-up instructions?  No  
(If yes, attach SDS with special instructions.)
  - e. Does the product contain DEHP?  No
- Is this product regulated for shipment by DOT?  No  
(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?  Yes

- Is this product regulated for shipment by IATA?  No  
(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?  Yes

- Is the product restricted for air shipment? If so, indicate restriction:
- Passenger
  - Cargo
  - Passenger & Cargo

Is this a reportable quantity?  No  
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);  
SP#

### ADD'L STORAGE INFORMATION

- Is the Product...
- Controlled Substance?  No      Controlled Substance Code
  - Controlled by State(s)?  No      Listed Chemical (List I or II)  No
  - ARCOS Reportable?  No      If yes, indicate which:
  - Schedule No.       Is it a scheduled listed chemical product?:  No

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes
- Restricted to retail pharmacy only:  No
- Restricted to hospital, clinics, and physician offices only:  No
- Restricted from US territories? (explain in comments)  No

Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard
- Aerosol Class; Identify NFPA Storage Level:
- Is the product a NIOSH hazardous drug?  No  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:       Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
If Yes, is it managed with a pharmacy registry?   
Website URL:

Med Guide Required  No  
Limited Distribution Requirement   
Comments / Details: (For example, iPledge program?)

**REMS:**

REMS Program Manager Name:       Phone:

Supplier Manages REMS registry exclusively:   
Wholesale distributor support:

Provider Name:       DEA #:

Site Enrollment Number assigned by Supplier:       PCPDP#:

NPI #:

Comments

**Registry:**

Registry Program Contact Name:       Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  800-397-9228

Is product returnable for credit:  Yes  
URL/Link to returns policy:  N/A

Special regulations or returns requirements for this product in certain states?  Yes

If so, which states? Other requirements? Comments?

Georgia, Mississippi, North Carolina. Requests can be made via fax: 815-624-7687 or email: customercare@tagipharma.com

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

