



October 26, 2018

Tagi Pharma  
722 Progressive Lane  
South Beloit, IL, 61080

Attn: Mr. Richard Waggoner

Dear Valued Customer:

In response to your Safety Data Sheet (SDS) request, according to OSHA Hazard Communications Standards 1910.1200(b)(6)(vii) and 1910.1200(b)(5)(iii), an SDS is not required for the requested product(s), as they are exempt from the Hazard Communications Standard.

NDC	Description
51224-102-50	Hydromorphone Hydrochloride Tablets, USP 8 mg, (100 Tablets)
51224-206-30	Naltrexone Hydrochloride Tablets, USP 50 mg, (30 Tablets)
51224-206-50	Naltrexone Hydrochloride Tablets, USP 50 mg, (100 Tablets)
51224-203-50	Phentermine Hydrochloride Capsules, USP 15 mg (100 Capsules)
51224-203-70	Phentermine Hydrochloride Capsules, USP 15 mg (1000 Capsules)
51224-202-50	Phentermine Hydrochloride Capsules, USP 30 mg (100 Capsules)
51224-202-70	Phentermine Hydrochloride Capsules, USP 30 mg (1000 Capsules)
51224-101-50	Phentermine Hydrochloride Tablets, USP 37.5 mg (100 Tablets)
51224-101-70	Phentermine Hydrochloride Tablets, USP 37.5 mg (1000 Tablets)

The above products are stored, prescribed, prepared, dispensed, administered, and disposed of according to the directions included within the product labeling and product packaging. The products are regulated by the Food and Drug Administration according to 21 CFR § 211.132.

If you have any questions or require additional product information, please contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Nadim Chaaraoui", is written over a light blue horizontal line.

Nadim Chaaraoui  
Sr. Manager QA and Compliance  
Elite Pharmaceuticals  
Phone: 201-660-7050 Ext. 214  
Fax: 201-660-7915  
Email: [nchaaraoui@elitepharma.com](mailto:nchaaraoui@elitepharma.com)



# Standard Pharmaceutical Product Information (Rx Product Only)

Final Version  Date: 9/1/2016

Introduction Type:  Post Launch Change

### PRODUCT INFORMATION

Company Name: TAGI Pharma, Inc.  
 Application Number for NDA/ANDA/BLA, Med Device: ANDA075274  
 Application: ANDA  
 Rx Product/Proprietary Name: Naltrexone Hydrochloride Tablets, USP  
 NDC: 51224-206-30  
 UPC:   
 MVX Code:   
 Description: Naltrexone Hydrochloride Tablets, USP 50mg  
 Active ingredients: Naltrexone Hydrochloride  
 URL for Additional Product Information: www.tagipharma.com

### FOR GENERIC DRUG PRODUCTS

i. Orange Book Rating: AB  
 ii. Brand Name: Naltrexone HCL  
 ReVia and Depade  
 Address 1: 722 Progressive Lane  
 South Beloit  
 State: IL  
 Zip: 61080  
 Address 2: Room 205  
 City: Melissa Bradley  
 Email: mbradley@tagipharma.com  
 Phone Number: 815-624-7685  
 Fax: 815-624-7014

### DRUG SUPPLY/CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  No  
 Is product exempt from DSCSA?  No  
 If yes, select exemption:  
 Other exemption - Write in:   
 Is product sold by manufacturer's exclusive distributor?  No  
 Are any waivers granted for product ID/barcode?  No  
 If Yes, attach documentation from FDA

### ORDER INFORMATION

What is the NDC selling unit?  
 1 bottle of 30 tablets  
 (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity? Yes  
 If Yes, how many of which package type?  
 12 Each  
 Inner/Outer/Case

### PHARMACY ORDER/BILL UNIT

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

### ADDITIONAL PRODUCT INFORMATION

Direct Ship Item  No  
 Legend Device?  No  
 State Control?  No  
 ARCOS reportable?  No  
 Co-Licensed?  No  
 Controlled Substance?  No  
 Schedule No.?  N/A  
 (incl. N for non-narcotic)  
 Hazardous Material/Cytotoxic Agent?  No  
 Is Item... Neither  
 If Unit Dose, is item bar coded to unit dose for hospital scanning?  
 Is it reverse numbered?

### WHOLESALE USE ONLY

Vendor #:  
 Whsl. Code #:  
 Fineline Code:

### REGULATORY AND STORAGE REQUIREMENTS

a. Temperature - Indicate the USP temperature range for this product.  
 I. Freezer - between -25 and -10 C (-13° - 14° F)  
 II. Cold - between 2 and 8 C (36° - 46° F)  
 III. Cool - between 8 and 15 C (46° - 59° F)  
 IV. Controlled Room - between 20 and 25 C (68° - 77° F)  
 allows for excursions between 15 and 30 C (59° - 86° F)  
 V. Avoid Excessive Heat - above 40 C (>104° F)  
 VI. Other Temperature Range Requirement  
 (write in)   
 VII. No Requirement  
 b. Contact for temperature excursion questions:  
 Name: Mat Maltis  
 Number: 815-624-7685  
 Is this product to be shipped to customers on ice?  No  
 Is this product to be shipped to customers on dry ice?  No  
 c. Special regulations for product in certain states?  
 Special returns requirements for this product?  
 No  
 No  
 d. Store product (unit of sale) upright?  
 Protect product (unit of sale) from light?  
 Yes  
 Yes  
 e. Shelf life: 24 Months  
 Initial shelf life at launch (if different):   
 Months

### COST INFORMATION

Regular Cost Per Unit of Sale (\$)  
 Invoice Cost (WAC) (\$)  
 Federal Excise Tax Per Unit of Sale

### ITEM AND PACKING INFORMATION

Weight Lbs.	Depth	Height	Width:	Volume (Cubes)	# Pieces:
Item: .9oz		2.5"	1.75"		
Box/ Carton:					
Case: 11oz	7.5"	1.75"	5.5"		
Pallet:					
UPC:					
Case:					
Carton:					

### WHOLESALE USE ONLY

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.  
 Signature: Melissa Bradley  
 As of date: 9/1/2016

### WHOLESALE USE ONLY

\*Please provide any additional information on page 2.



# Standard Pharmaceutical Product Information (Page 2)

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  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No  No

<input type="checkbox"/>	Carcinogen
<input type="checkbox"/>	Reproductive Toxicant
<input type="checkbox"/>	Both
<input type="checkbox"/>	Warning appears on label

- c. Contact Hazard?  No  No  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No  No  No
- e. Does the product contain DEHP?  No  No  No

EPA Hazardous Waste Code:	
Hazardous Waste Identification	

Is this product regulated for shipment by the DOT?  No  No

Is this a reportable quantity?  No  No

RQ Threshold:

Is this product shipped utilizing an authorized DOT exception or Special Permit?  No  No

(If yes, identify method below)

<input type="checkbox"/>	Limited Quantity
<input type="checkbox"/>	Consumer Commodity, ORM-D
<input type="checkbox"/>	Small Quantity (49 CFR 173.4)
<input type="checkbox"/>	Special Permit, DOT-SP
<input type="checkbox"/>	Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/>

Is the product restricted for air shipment? If so, indicate restriction:

<input type="checkbox"/>	Passenger
<input type="checkbox"/>	Cargo
<input type="checkbox"/>	Passenger & Cargo

### ADDITIONAL STORAGE INFORMATION

Please check as appropriate for this product.

<input type="checkbox"/>	Organic	<input type="checkbox"/>	Inorganic
<input type="checkbox"/>	Antineoplastic	<input type="checkbox"/>	Steroid/Androgen
<input type="checkbox"/>	Corrosive	<input type="checkbox"/>	Oxidizer
<input type="checkbox"/>	Aerosol Class; Identify NFPA Storage Level: <input type="text"/>		

Listed Chemical (List I or II) (Indicate or Write-in below):

<input type="checkbox"/>	Ephedrine
<input type="checkbox"/>	Pseudoephedrine
<input type="checkbox"/>	Phenylpropanolamine
<input type="checkbox"/>	tocaine (±2.2%)
<input type="checkbox"/>	Other: <input type="text"/>

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No

Restricted to retail pharmacy only:  No  No

Restricted to hospital, clinics, and physician offices only:  No  No

Restricted from US territories? (explain in comments)  No  No

Comments:

(if yes, answer a-d below and provide SDS)

- a. DOT Hazard Class
- b. UN/ID Number
- c. Packing Group
- d. Inhalation Hazard?

### ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized? <input type="checkbox"/>	No	Level	2D	Linear	RFID
If not, when? <input type="text"/>	11/1/2017	Item	2D	Linear	RFID
Items aggregated to case? <input type="checkbox"/>		Box/Case	2D	Linear	RFID
		Pallet	2D	Linear	RFID

GTIN-14

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:  Yes  No

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  Yes  No

If so, which states? Other requirements? Comments?

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

### ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:  N/A

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



# Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete. Standard Order Receipt and Processing

**Order Method for Designated Drop Ship Product**

Purchase orders may be accepted by:

a. EDI  Yes

b. Autofax  Yes

c. Fax  Yes

d. Phone only  Yes

e. Supplier Web Site only  No

Minimum Order Quantity: 12 Bottles

Supplier's Customer Service Number: 800-397-9228

Contracted 3PL company / contact #: \_\_\_\_\_

Name: \_\_\_\_\_

Phone: \_\_\_\_\_

Purchase order daily receipt cut off time by supplier: 12:00 PM

Cut off time: \_\_\_\_\_

Shipping lead time of PO: \_\_\_\_\_

Hours: \_\_\_\_\_

Days: \_\_\_\_\_

Ships same day for next day receipt:  No

Ships for second day receipt:  No

Ships regular ground for 3-10 days receipt:  Yes

**Expedited Freight Charges or Other Designated Drop Ship Fees:**

Expedited freight fees billed with each order:  Yes  No

Drop Ship service fee billed with each order:  Yes  No

Drop Ship miscellaneous fees billed:  Yes  No

Comments: \_\_\_\_\_

**Overnight and Priority Overnight PO Processing**

Overnight receipt available:  Yes  No

PO Receipt cut off time: 12:00 PM

Days of week overnight is available:

Monday	<input checked="" type="checkbox"/>
Tuesday	<input checked="" type="checkbox"/>
Wednesday	<input checked="" type="checkbox"/>
Thursday	<input checked="" type="checkbox"/>
Friday	<input checked="" type="checkbox"/>

Priority Overnight receipt available:  Yes  No

PO Receipt Cut off time: 12:00 PM

Saturday Overnight receipt available:  Yes  No

PO Receipt Cut off time: \_\_\_\_\_

Order receipt method: Phone #: \_\_\_\_\_ Fax #: \_\_\_\_\_

EDJ: \_\_\_\_\_

Overnight Fees apply:  Yes  No

Other fees apply: \_\_\_\_\_

**Class of Trade Restriction:**

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:  Yes  No

Restricted to hospital, clinics, and physician offices only:  No  No

Restricted from US territories? (explain in comments)  No

Comments: \_\_\_\_\_

**Return Instructions**

Contact # if product is received damaged: 800-397-9228

Is product returnable for credit:  Yes  No

URL/Link to returns policy: N/A

Special regulations or returns requirements for this product in certain states?  Yes  No

If so, which states? Other requirements? Comments? \_\_\_\_\_

**REMS or Registry Restrictions**

REMS Program Manager Name: \_\_\_\_\_ No \_\_\_\_\_

Supplier Manages REMS registry exclusively: \_\_\_\_\_

Wholesale distributor support: \_\_\_\_\_

Provider Name: \_\_\_\_\_

Site Enrollment Number assigned by Supplier: \_\_\_\_\_

DEA #: \_\_\_\_\_

PCPDP #: \_\_\_\_\_

NP1 #: \_\_\_\_\_

Comments: \_\_\_\_\_

Registry Program Contact Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Comments: \_\_\_\_\_

**Additional Information**

Is product order for scheduled patient procedure? \_\_\_\_\_

Is product order for restocking purposes? \_\_\_\_\_

Miscellaneous Notes: \_\_\_\_\_

**Other Data Information Required to Process PO:**

Patient Procedure Date: \_\_\_\_\_

Physician Name: \_\_\_\_\_

Physician/Clinic Phone #: \_\_\_\_\_

Physician State License #: \_\_\_\_\_

Physician/Clinic DEA #: \_\_\_\_\_

Physician/Clinic Specialty: \_\_\_\_\_