

SAFETY DATA SHEET

COMPANY NAME AND ADDRESS:

APICORE US LLC
49 Napoleon Court
Somerset, NJ 08873
732-748-8882
Fax: 732-748-8929

1. IDENTIFICATION

Material: Tetrabenzine Tablets, 12.5 mg and 25 mg

Manufacturer: Ingenus Pharmaceuticals NJ, LLC, 140 New Dutch Lane, Fairfield, NJ 07004

Distributor: Tagi Pharma Inc., 722 Progressive Lane # 205, South Beloit, IL 61080

2. HAZARD(S) IDENTIFICATION

Harmful by ingestion. Harmful if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Tetrabenazine, CAS Number 58-46-8

4. FIRST AID MEASURES

General: Consult a Physician. Show this safety data sheet to the doctor in attendance.

Inhalation: If inhaled remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Swallowed: If swallowed, wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention.

Eyes contact: In case of contact with eyes, hold eyelids apart and flush eyes with plenty of water for at least 20 minutes. Call a Physician if any adverse effects occur.

Skin contact: In case of skin contact, wash skin with soap and plenty of water. Consult a Physician.

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5. FIRE FIGHTING MEASURES

Flammability of the Product:	Not Available..
Auto-Ignition Temperature:	Not available.
Flash Points:	Not available.
Extinguishing Media:	Use water spray, alcohol-resistant foam, carbon dioxide or dry chemical spray.
Protective equipment:	Wear self-contained breathing apparatus for firefighting necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.
Environmental Precautions:	Do not let product enter drains.
Clean-up Methods:	Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Handling:	Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation.
Storage:	Store at 25° C (77° F) with excursions permitted between 15° to 30° C (59° to 86° F) [USP controlled Room Temperature].

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Tetrabenazine Tablets 12.5 mg
White cylindrical biplanar tablets with bevelled edges, debossed '707' on one side and plain on the other side.
Bottle of 112 Tablets, NDC 51224-425-10

Tetrabenazine Tablets 25 mg
Yellowish-buff, cylindrical biplanar tablets with bevelled edges, debossed '708' on one side and scored on the other side.
Bottle of 112 Tablets, NDC 51224-426-10

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10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Acute toxicity: LD50 Oral – mouse – 550 mg/kg

Carcinogenicity: Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA. See actual entry in RTECS for complete information.

Reproductive toxicity: Reproductive toxicity – rat – Subcutaneous

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

Dispose of in a manner consistent with federal, state, and local regulations.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT) - Not dangerous goods

IDMG – Not dangerous goods

IATA – Not dangerous goods

15. REGULATORY INFORMATION

OSHA Hazards

Harmful by ingestion.

DSL Status

This product contains the following components that are not on the Canadian DSL nor NDSL lists.

Tetrabenazine, CAS-No.: 58-46-8

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SARA 302 Components

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

Tetrabenazine, CAS-No.: 58-46-8

New Jersey Right To Know Components

Tetrabenazine, CAS-No.: 58-46-8

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Apicore US LLC shall not be held liable for any damage resulting from handling with this product. Apicore US LLC reserves the right to revise this SDS.



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: Post Launch Change Final Version Date: 7/28/2017

PRODUCT INFORMATION

Company Name: **TAGI Pharma, Inc.** Application: ANDA

Application Number for NDANDA/DA/BLA, Med Device: **A207682**

Rx Product/Proprietary Name: **Tetrabenazine Tablets** UPC:

NDC: **61224-426-10** MVX Code:

CVX Code:

Description: **Tetrabenazine Tablets 25mg, 112 Tablets**

Active Ingredients: **Tetrabenazine**

URL for Additional Product Information: **www.tagipharma.com**

Address: **722 Progressive Lane** Address 2: **Room 205**

City: **South Beloit** State: **IL** Zip: **61080**

Key Contact: **Melissa Bradley** Email: **mbradley@tagipharma.com**

Phone Number: **815-624-7685** Fax: **815-624-7687**

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: **AB** II. Brand Name: **Xenazine**

III. Generic Equivalent for Brand: **Tetrabenazine Tablets**

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No

Is product exempt from DSCSA? Yes No

If yes, select exemption: Other exemption - Write in: _____

Is product repackaged? No Yes

Is product sold by manufacturer's exclusive distributor? No Yes

Are any waivers granted for product ID/barcode? No Yes

If Yes, was original product purchased direct from mfr? Yes No

If Yes, attach documentation from FDA _____

DUNS: **963322560**

ADDITIONAL PRODUCT INFORMATION

Is the Product... Direct Ship Item No

Legend Device? No

State Control? No

ARCOS reportable? No

Co-Licensed? No

Controlled Substance? No

Schedule No. 7 No

(Incl. N for non-narcotic)

Controlled Substance Code: N/A No

Hazardous Material/Cytotoxic Agent? No

Is Item... Neither No

If Unit Dose, is item bar coded to unit dose for hospital scanning? No

Is it reverse numbered? No

WHOLESALE USER ONLY

Vendor #: _____

Whsi. Code #: _____

Fineline Code: _____

Unit of Sale: Bottle Box/ Carton

Amplule Glass Tube

Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Powder Multi Other: Write in _____

Minimum order quantity? Yes No

If Yes, how many of which package type? Each Inner/ Carton/ Pack Case

Rec. sell unit to customer? (Write-in, e.g. 1 Vial)

Size/Strength/Form: **25mg / 112 Tablets**

Product Shape: **Cylindrical biconvex**

Product Color: **Tablets with beveled Yellowish-buff**

Product Imprint: **708 on one side and scored on other side**

PHARMACY ORDER / BILL UNIT

What is the NDC selling unit? **1 Bottle of 112 Tablets**

What is the NDC selling unit? **(Write-in, e.g. 1 Box of 10 Vials)**

Other Product Information

Regular Cost Per Unit of Sale (\$) **\$7,324.88**

Invoice Cost (WAC) (\$) **\$7,324.88**

Federal Excise Tax Per Unit of Sale **\$1,720.17**

COST INFORMATION

SPECIAL HANDLING 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: **Mal Mathis**

Number: **815-624-7685**

Is this product to be shipped to customers on ice? No Yes

Is this product to be shipped to customers on dry ice? No Yes

c. Special regulations for product in certain states? No Yes

Special returns requirements for this product? No Yes

d. Store product (unit of sale) upright? No Yes

Protect product (unit of sale) from light? No Yes

e. Shelf life: 24 Months Initial shelf life at launch (if different): _____ Months

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Depth	Height	Width:	Volume (Cubes)	# Pieces:
Box/ Carton:	1.05oz		3.2"	1.5"		
Case:						
Pallet:						
Case:						
Carton:						

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?
 Carcinogen No
 Reproductive Toxicant
 Both

c. Contact Hazard? No
 Warning appears on label

d. Does this product require special clean-up instructions?
 (If yes, attach SDS with special instructions) No

e. Does the product contain DEHP? No

Hazardous Waste Identification

EPA Hazardous Waste Code: _____

Is this product regulated for shipment by the DOT?
 No

Is this a reportable quantity?
 RO Threshold: _____ No

Is this a marine pollutant?
 Is this product shipped utilizing an authorized DOT exception or Special Permit?
 (If yes, identify method below) No

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

a. DOT Hazard Class _____

b. UN/ID Number _____

c. Packing Group _____

d. Inhalation Hazard? _____

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# _____

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	No	Level	2D	How?	RFID	GTIN-14
If no, when?	11/12/2017	Item	2D	Linear	RFID	
Items aggregated to case?		Box/Caron	2D	Linear	RFID	
		Case	2D	Linear	RFID	
		Pallet	2D	Linear	RFID	

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

Passenger

Cargo

Passenger & Cargo

REMS or REGISTRY/RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?
 Website URL: _____

Comments / Details: (For example, pledge program?) _____

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

Aerosol Class: Identify NFPA Storage Level: _____

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 and North Carolina. Requests can be made via fax: 815-624-7687 or email: customercare@teqpharma.com

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

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (2.2.2%)

Other: _____

ADDITIONAL INFORMATION

if Unit Dose NDC, indicate NDC here: _____ N/A

MISCELLANEOUS NOTES and/or image of Product Barcode:

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: _____

Release DATE _____



Standard Pharmaceutical Product Information (Page 3)

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

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI	Yes	Fax Number:	815-624-7687
b. Autofax	Yes	Fax Number:	815-624-7687
c. Fax	Yes	Phone No.:	800-397-9228
d. Phone only	Yes	Site Address:	
e. Supplier Web Site only	No		

Minimum Order Quantity: 1 bottle
 Supplier's Customer Service Number: 800-397-9228
 Contacted 3PL company / contact #: _____
 Name: _____
 Phone: _____

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier: Central

Cut off time: Hours Days

Shipping lead time of PO: 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

Drop Ship service fee billed with each order: No

Drop Ship miscellaneous fees billed: No

Comments: _____

Overnight and Priority Overnight PO Processing

Overnight receipt available: Yes

PO Receipt cut off time: Central

Days of week overnight is available:

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

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: _____

Priority Overnight receipt available:

PO Receipt Cut off time: Yes

Saturday Overnight receipt available: No

Order receipt method: Phone #: _____

EDI: Fax #: _____

Overnight Fees apply: _____

Other fees apply: _____

REMS or Registry Restrictions

REMS: No

REMS Program Manager Name: _____ Phone: _____

Supplier Manages REMS registry exclusively: _____

Wholesale distributor support: _____

Provider Name: _____

Site Enrollment Number assigned by Supplier: _____

DEA #: _____

PCPDP #: _____

NPI #: _____

Comments: _____

Registry: _____

Registry Program Contact Name: _____ Phone: _____

Comments: _____

Return Instructions

Contact # if product is received damaged: Yes

Is product returnable for credit: Yes

URL/link to returns policy: _____

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

If so, which states? Other requirements? Comments? _____

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure? _____

Is product order for restocking purposes? _____

Miscellaneous Notes: _____

Other Data Information Required for Process PO: _____

Patient Procedure Date: _____

Physician Name: _____

Physician/Clinic Phone #: _____

Physician State License #: _____

Physician/Clinic DEA #: _____

Physician/Clinic Specialty: _____