

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 biphenar 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 biphenar 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:

PRODUCT INFORMATION

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

Application Number for NDA/ANDA/B/L/A, Med Device: **A207682**

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

NDC: **51224-425-10** MAX Code:

CXA Code:

Description: **Tetrabenazine Tablets 12.5mg, 112 Tablets**

Active ingredients: **Tetrabenazine**

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

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

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

Key Contact: **Melissa Bradley** Email: **mbradley@taigipharma.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 (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No **DUNS: 963322560**

Is product exempt from DSCSA? No

If yes, select exemption:

Other exemption - Write in:

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

Is product sold by manufacturer's exclusive distributor? No Yes **If Yes, attach documentation from FDA**

Are any waivers granted for product ID/barcode? No Yes **If Yes, attach documentation from FDA**

ADDITIONAL PRODUCT INFORMATION

Is the Product... Legend Device? No Yes

State Control? No Yes

ARCOS reportable? No Yes

Co-licensed? No Yes

Controlled Substance? No Yes

Schedule No.?

(incl. N for non-narcotic)

Controlled Substance Code:

Hazardous Material/Cytotoxic Agent? No Yes

Is Item... Neither Yes No

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

Is it reverse numbered? Yes No

ORDER INFORMATION

Unit of Sale: Bottle Box/ Carton Ampule Glass Tube

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

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type? **1**

Each Inner/ Carton/ Pack Case

ITEM/AND PACKING INFORMATION

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

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

VII. No Requirement (write in)

b. Contact for temperature excursion questions: **Mat Mathis**

Name: **815-624-7685**

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? Yes No

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

e. Shelf life: Months

Initial shelf life at launch (if different): Months

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

Rx Billing unit to pharmacy: Each Gram Milliliter

Other Product Information

Size/Strength/Form: **12.5mg / 112 Tablets**

Product Shape: **Cylindrical Imprinted**

Product Color: **Tablets with beveled white**

Product Imprint: **707**

COST INFORMATION

Regular Cost Per Unit of Sale (\$)

Invoice Cost (WAC) (\$)

Federal Excise Tax Per Unit of Sale

As of date:

WHOLESALE USE ONLY

Vendor #:

Whsl. Code #:

Fineline Code:

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

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

Carcinogen
 Reproductive Toxicant
 Both

c. Contact Hazard? No

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

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? 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#

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

Passenger
 Cargo
 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

Aerosol Class: Identify NFPA Storage Level:

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

<input type="checkbox"/>	Ephedrine
<input type="checkbox"/>	Pseudoephedrine
<input type="checkbox"/>	Phenylephrine
<input type="checkbox"/>	Iodine (2.2%)
<input type="checkbox"/>	Other: <input type="text"/>

CLASS OF TRADE RESTRICTION

No restriction: Select YES if sold to retail pharmacy, hospital, 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:

ADDITIONAL PRODUCT INFORMATION: Serialization

Serialized?	<input type="checkbox"/> No	<input type="checkbox"/> Level	<input type="checkbox"/> 2D	<input type="checkbox"/> Flow?	<input type="checkbox"/> RFID	<input type="checkbox"/> GTIN-14
If not, when?	<input type="text"/> 11/12/2017	<input type="checkbox"/> Box/Caron	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>
Items aggregated to case?	<input type="checkbox"/>	<input type="checkbox"/> Case	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>
		<input type="checkbox"/> Pallet	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>

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?')

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

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?

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

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

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**

Purchase orders may be accepted by:

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

Minimum Order Quantity: 1 bottle
 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 Central
 Shipping lead time of PO: _____ Hours _____ Days
 Ships same day for next day receipt: _____ No
 Ships for second day receipt: _____ Yes
 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: 12:00 PM Central
 Days of week overnight is available: _____
 Priority Overnight receipt available: Yes _____
 PO Receipt Cut off time: 12:00 PM
 Saturday Overnight receipt available: No _____
 PO Receipt Cut off time: _____
 Order receipt method: Phone #: _____ Fax #: _____
 EDI: _____
 Overnight Fees apply: _____
 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 _____
 Restricted to hospital, clinics, and physician offices only: No _____
 Restricted from US territories? (explain in comments): No _____

Comments: _____

Return Instructions

Contact # if product is received damaged: 800-597-9228 Yes
 Is product returnable for credit: N/A 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? _____

REMS or Registry Restrictions

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: _____

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: _____
