



Standard Pharmaceutical Product Information (Rx Product Only)

Final Version **Date:** 02/7/2019

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

PRODUCT INFORMATION

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

Application Number for NDA/ANDA/BLA (drug): PMA1510 (k)(med device) **Application:** ANDA

DUNS: 51224-220-30 **Individual Unit NDC:** **UFC:**

Proprietary Name (if Applicable) and Established Name: Metformin Hydrochloride Immediate-Release Tablets, USP **CVX Code:**

Selling Unit NDC: **MXV Code:**

UDI:

Description: Metformin IR 1000mg 100 count

Active Ingredient(s): Metformin IR

URL for Additional Product Information: www.tagi-pharma.com

Address: 722 Progressive Lane **State:** IL **Room 205**

City: South Beloit **Zip:** 61080

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

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

Product Therapeutic Classification:

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device? No
 reverse numbered? No
 co-licensed? No
 Is the Product...
 Direct-Ship Only No
 Neither No

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

If Unit Dose NDC, indicate NDC here:

Country of Origin: China

Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 100

Strength: 1000mg

Dosage Form: Tablet

Product Shape: Round

Product Color: White

Product Imp rint:

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

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

Is product exempt from DSCSA? No Yes

If yes, select exemption:
 Other exemption - Write In:

Is product repackaged? No Yes

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

Has FDA granted waiver/exception/exemption for product? No Yes

GTIN PRODUCT INFORMATION

Item	Level	Unit	Quantity
<input checked="" type="checkbox"/>	Box/ Carton/Bundle/Inner Pack	20	<input type="text"/>
<input checked="" type="checkbox"/>	Case	20	<input type="text"/>
<input checked="" type="checkbox"/>	Pallet	20	<input type="text"/>
<input type="checkbox"/>		20	<input type="text"/>
<input type="checkbox"/>		20	<input type="text"/>
<input type="checkbox"/>		20	<input type="text"/>
<input type="checkbox"/>		20	<input type="text"/>
<input type="checkbox"/>		20	<input type="text"/>
<input type="checkbox"/>		20	<input type="text"/>
<input type="checkbox"/>		20	<input type="text"/>

Serialized? Yes No

If not, when?

Items aggregated? No Yes

PHARMACY ORDER / BILL UNIT

Rx billing unit to pharmacy:

Each

Gram

Milliliter

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Depth	Height	Width	Volume (Cubes)	# Pieces:
Box/Carton/Bundle/Inner Pack:	0.32		3.77	1.87		1
Case:	1.92		22.44	16.92		6
Pallet:	46.29		14.17			144
UPC:						
Case:						
Carton:						

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$) \$10.15 **Whst. Code #:**

Federal Excise Tax Per Unit of Sale

As of date: 7/5/2019

WHOLESALE USE ONLY:

Vendor #:

Finaline Code:

Signature: Melissa Bradley

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

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

ORDER INFORMATION

What is the NDC selling unit?

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

Minimum order quantity?

If Yes, how many of which package type?
 12 Each Yes
 Inner/ Carton/ Pack Yes
 Case No
 24 Months No

ADDITIONAL INFORMATION

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

CONTACT FOR TEMPERATURE EXCURSION QUESTIONS:

Name:

Number: 815-624-7685

Group E-mail: druginfo@tagipharma.com

SPECIAL REGULATIONS FOR PRODUCT IN ANY STATES?

Special returns requirements for this product? No Yes

Store product (unit of sale) upright? Yes No

Protect product (unit of sale) from light? (if different):

Initial shelf life at launch (if different):

WHOLESALE USE ONLY:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*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

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?
 No

c. Contact Hazard? No

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

e. Does the product regulated for shipment by DOT or 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?
 No

SDS Hazard Classification

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen Contact Hazard

Aerosol Class: Identify NFPA Storage Level: _____

Is the product a NIOSH hazardous drug?
 If yes, indicate which: _____

EPA Hazardous Waste Code: _____

Hazardous Waste Identification _____

REMS or REGISTRY RESTRICTIONS

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

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

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 tel. # if product received damaged: 855-225-8244

Is product returnable for credit: Yes

URL/link to returns policy: _____
 Yes

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

ADD'L STORAGE INFORMATION

Is the Product...
 Controlled Substance? No
 Controlled by State(s)? No
 ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic) _____
 Controlled Substance Code _____
 Listed Chemical (List I or II) _____
 If yes, indicate which: _____
 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
 Restricted to retail pharmacy only: Yes
 Restricted to hospital, clinics, and physician offices only: No
 Restricted from US territories? (explain in comments) No
 Comments: _____

MISCELLANEOUS NOTES and/or Image of Product Barcode:

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 No

b. Autofax Yes No

c. Fax Yes No

d. Phone only Yes No

e. Supplier Web Site only Yes No

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #:

Fax Number:

Phone No.:

Site Address:

Name:

Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier:

Cut off time:

Shipping lead time of PO:

Hours:

Days:

Ships same day for next day receipt:

Ships for second day receipt:

Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

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 type="checkbox"/>

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Phone:

Fax:

EDI:

Overnight Fees apply:

Other fees apply:

Return Instructions

Contact # if product is received damaged:

Is product returnable for credit:

URL/link to returns policy:

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

If so, which states? Other requirements? Comments?

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

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #:

Physician State License #:

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY/UNDERTAKING

Trade name : Metformin Tablets

Company Identification: CSPC OUYI PHARMACEUTICAL CO., LTD.

Emergency tel: 0311-87896581

Issue Date : 12/10/2015.

2. HAZARDS IDENTIFICATION

Risk Phrases : Harmful in contact with skin and if swallowed. - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Adverse human health effects : Damage to liver. This material may induce blood disorders and/or aggravate pre-existing blood disorders. Cardiac disorders. Exposure may produce an allergic reaction. Hypoglycaemia. Gastrointestinal disorders.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components : This product is hazardous.

Substance name Contents CAS No EC No Annex No Classification

Metformin hydrochloride:1115-70-4214-230-6-----Xn; R21/22R52-53

CSPC OUYI PHARMACEUTICAL CO., LTD.
石药集团欧意药业有限公司

4. FIRST AID MEASURES

First aid measures

- Inhalation:Assure fresh air breathing. Rest. If you feel unwell, seek medical advice.- Skin contact:Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.- Eye contact:Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persist.- Ingestion:Rinse mouth. If swallowed, seek medical advice immediately and show this container or label. In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

5. FIRE FIGHTING MEASURES

Extinguishing media- Suitable extinguishing media:Water spray. Carbon dioxide. Dry powder.

- Unsuitable extinguishing media:Do not use a heavy water stream. Surrounding fires:Use water spray or fog for cooling exposed containers. Protection against fire:Do not enter fire area without proper protective equipment, including respiratory protection. Hazardous combustion products:Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

6. ACCIDENTAL RELEASE MEASURES

General precautions:Remove ignition sources. Evacuate area. Personal precautions:Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Clean up methods:To clean the floor and all objects contaminated by this material, use : Water. /Detergent. Avoid dust production. Ensure adequate ventilation.

7. HANDLING AND STORAGE

Personal protection:Avoid all unnecessary exposure. Ensure prompt removal from eyes, skin and clothing. Technical protective measures:Material should be handled in a laboratory hood whenever possible. Handling:Handle in accordance with good industrial hygiene and safety procedures. Storage:METFORMIN HYDROCHLORIDE CRS is not intended for long-term storage.

Keep container tightly closed in a cool, well ventilated place. Storage - away from:All heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials, see §10

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protection= 8 :- Respiratory protection:Wear approved mask. (P2) In case of insufficient ventilation, wear suitable respiratory equipment.- Hand protection:Wear suitable gloves resistant to chemical penetration.- Skin protection:Wear suitable protective clothing.- Eye protection:Chemical goggles or safety glasses. Industrial

hygiene:Provide local exhaust or general room ventilation.

9. PHYSICAL AND CHEMICALS PROPERTIES

Chemical formula:C₄H₁₂N₅Molecular weight:165.6Physical state at 20 °C:Crystals.Colour:White.pH value:6.68 (1%)Melting point [°C]:222 - 226Boiling point [°C]:No data available.
Solubility in water:Complete.Flash point [°C]:No data available.Log P octanol / water at 20°C:-2.64

10 STABILITY AND REACTIVITY

Stability and reactivity:Stable under normal conditions.Materials to avoid:Alkali. Strong oxidizers.Conditions to avoid:None known.Hazardous decomposition products:Carbon monoxide. Carbon dioxide. Nitrogen oxides. Chlorides.When heated to decomposition, emits dangerous fumes.Hazardous reactions:None under normal conditions.Hazardous polymerization:Will not occur.

11. TOXICOLOGICAL INFORMATION

RTECS nr:DU1800000 (See actual entry in RTECS for complete information.)Rat oral LD50 [mg/kg]:1770Rabbit dermal LD50 [mg/kg]:No data available.Rat inhalation LC50 [mg/L/4h]:No data available.Acute toxicity:Cardiac disorders. Hypoglycaemia. Gastrointestinal disorders. This material may induce blood disorders and/or aggravate pre-existing blood disorders.Chronic toxicity:Damage to liver.Sensitization:No data available.

12. ECOLOGICAL INFORMATION

Ecological effects information:Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.LC50-96 Hour - fish [mg/L]:No data available.EC50-48 Hour-Daphnia magna [mg/L]:52IC50-72h-Algae [mg/L]:No data available.Biodegradation [%]:No data available.Persistence - degradability:Partially biodegradable.Log P octanol / water at 20°C:-2.64 (metformin)Bioaccumulative potential:No data available.

13. DISPOSAL CONSIDERATIONS

General:Dispose of this material and its container at hazardous or special waste collection point.Dispose in a safe manner in accordance with local/national regulations.

14. TRANSPORT INFORMATION

Transport regulation UN Classification: UN number shipping name – Class (other risk)– PG

IATA/ICAO (air) Not classified

ADR/RID (road/railway) Not classified

IMDG (sea) Not classified

Marine pollutant: None-hazardous for sea transport.

15. REGULATORY INFORMATION

Symbol(s):Xn : HarmfulR Phrase(s):R21/22 : Harmful in contact with skin and if swallowed.R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.S Phrase(s):S24 : Avoid contact with skin.S36/37 : Wear suitable protective clothing and gloves.S51 : Use only in well-ventilated areas.S59 : Refer to manufacturer/supplier for information on recovery/recycling.S61 : Avoid release to the environment. Refer to special instructions/Safety datasheets.

16. OTHER INFORMATION

Further information:Revision - See : *List of relevant R phrases:R21/22 : Harmful in contact with skin and if swallowed.R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

EXPIRY DATE: 01/24/2018

CSPC OUYI PHARMACEUTICAL CO.,LTD.
石药集团欧意药业有限公司