



Standard Pharmaceutical Product Information (Rx Product Only)

Final Version	Date: 02/27/2010	Introduction Type:	New Item	PRODUCT INFORMATION																																	
Company Name: TAGI Pharma, Inc. Application Number for NDA/ANDA/BLA (drug): PMA1510(x)(med device) DUNS: A205098 Application: ANDA		Proprietary Name (if Applicable) and Established Name: Meformin Hydrochloride Immediate-Release Tablets, USP Selling Unit NDC: 51224-220-90 Individual Unit NDC: _____ UPC: _____ CVX Code: _____ UDI: _____																																			
Description: Meformin IR 1000mg 500 count Active Ingredient(s): Meformin IR		URL for Additional Product Information: www.tagipharma.com Address: 722 Progressive Lane City: South Babot State: _____ Room: 205 Zip: 61060 Key Contact: Melissa Bradley Phone Number: 815-824-7685 Product Therapeutic Classification: _____																																			
Is the Product... a legend device? No revers numbered? No co-licensed? No is the Product... Direct-SHIP Only? No is the Product... Neither? No		PRODUCT DESCRIPTION INFORMATION Size: 500 Strength: 1000mg Dosage Form: Tablet Product Shape: Round Product Color: White Product Imprint: _____																																			
If Unit Dose, is item bar coded to unit dose for hospital scanning? _____ If Unit Dose NDC, indicate NDC here: _____ Country of Origin: China Is this product covered under the Trade Agreements Act (TAA)? No		FOR GENERIC DRUG PRODUCTS I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: _____ <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable																																			
Does supplier meet DSCSA definition of manufacturer? _____ Is product exempt from DSCSA? _____ If yes, select exemption: _____ Other exemption - Write in: _____ Is product repackaged? No Is product sold by manufacturer's exclusive distributor? No Has FDA granted waiver/exemption for product? No		DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION GLN: _____ Level: No Item: X Box/Case/Bundle/Inner Pack: X Case: X Pallet: X																																			
SerIALIZED? Yes If not, when? _____ Items aggregated? _____		ITEM AND PACKING INFORMATION <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Item:</th> <th>Weight Lbs.</th> <th>Dimensions (US mmm.)</th> <th>Depth</th> <th>Height</th> <th>Width</th> <th>Volume (Cubs)</th> <th># Pieces:</th> </tr> </thead> <tbody> <tr> <td>Box/Case/Bundle/Inner Pack:</td> <td>1.56</td> <td>4.078</td> <td>2.825</td> <td></td> <td></td> <td></td> <td>1</td> </tr> <tr> <td>Case:</td> <td>9.36</td> <td>14.96</td> <td>16.14</td> <td>12.59</td> <td></td> <td></td> <td>6</td> </tr> <tr> <td>Pallet:</td> <td>37.47</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td>24</td> </tr> </tbody> </table>				Item:	Weight Lbs.	Dimensions (US mmm.)	Depth	Height	Width	Volume (Cubs)	# Pieces:	Box/Case/Bundle/Inner Pack:	1.56	4.078	2.825				1	Case:	9.36	14.96	16.14	12.59			6	Pallet:	37.47						24
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Specialized Product Information Specialized Product (unit of sale) upright? _____ Protect product (unit of sale) from light? (if different): _____ Initial shelf life at launch (if different): _____ Months: _____ Months: _____		ORDER INFORMATION Unit of Sale: X 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? _____ Each: _____ Inner/Case/Pack: _____ Other: Write In: _____																																			
Special regulations for product in any states? _____ Special returns requirements for this product? _____ Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No		PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? _____ (Write-in, e.g. 1 Vial) _____ Rx billing unit to pharmacy: _____ Each: _____ Gram: _____ Milliliter: _____																																			
Additional Information Other Temperature Range Requirement (write in): _____ Other Temperature Range Requirement (write in): _____		COST INFORMATION Regular Cost: _____ Invoice Cost (WAC) (\$): \$48.25 Federal Excise Tax Per Unit of Sale: 7/5/2019 As of date: _____ Vendor #: _____ Whse. Code #: _____ Freight Code: _____																																			
Signature: _____ Name: Melissa Bradley		WHOLESALE USE ONLY: Signature: _____ Name: Melissa Bradley																																			

*Please provide any additional information on page 2.

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

See new p. 3 for Designated Drop Ship Only.



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

Is this 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

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

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity? No

RQ Threshold: No

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
(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 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 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?
if yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

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

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

REMS:

REMS Program Manager Name: No
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name:
Site Enrollment Number assigned
by Supplier:

Phone:

DEA #:

PCPDP #:

NPI #:

Comments

Registry:

Registry Program Contact Name:

Comments

Phone:

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@legipharma.com)

MISCELLANEOUS NOTES and/or Image or 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	
b. Autofax	Yes	815-624-7687
c. Fax	Yes	815-624-7687
d. Phone only	No	855-225-8244
e. Supplier Web Site only	No	
Minimum Order Quantity:		
Supplier's Customer Service Number:		855-225-8244
Contracted 3PL company / contact #:	Name:	
	Phone:	

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:

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:

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:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier: 12:00pm Central Days

Shipping lead time of PO: Hours Days

Ships same day for next day receipt: No No Yes

Ships for second day receipt: No No Yes

Ships regular ground for 3-10 days receipt:

Overnight and Priority Overnight PO Processing

Overnight receipt available: Yes No

PO Receipt cut off time: 12:00pm Central

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: 12:00pm Yes No

Saturday Overnight receipt available:

PO Receipt Cut off time: No

Phone: 855-225-8244 Phone #:

Fax: 815-624-7687 Fax #:

EDI: Yes No

Overnight Fees apply:

Other fees apply: Yes No

Return Instructions

Contact # if product is received damaged: 855-225-8244

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

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