



Standard Pharmaceutical Product Information (Rx Product Only)

Final Version: Date: 02/27/2019

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature - Indicate the USP temperature range for this product:
 Temperature Range: _____
 Controlled Room - between 20 and 25 C (68° - 77° F)
 Other Temperature Range Requirement: _____
 (write in)

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

b. Contact for temperature excursion questions:
 Name: Mat Methis
 Number: 815-824-7885
 Group E-mail: dmjinfo@lagpharma.com

c. Special regulations for product in any states?
 Special returns requirements for this product? No Yes

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

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

Introduction Type: New Item

Application: ANDA

Proprietary Name (if applicable) and Established Name: Meformin Hydrochloride Immediate-Release Tablets, USP
 Selling Unit NDC: 51224-020-70 Individual Unit NDC: _____
 Cvx Code: _____ MYX Code: _____

Description: Meformin IR 500mg 1000 count

Active Ingredient(s): Meformin IR

URL for Additional Product Information: www.lagpharma.com

Address: 722 Progressive Lane
 City: South Bolit
 Key Contact: Melissa Bradley
 Phone Number: 815-824-7885
 Product Therapeutic Classification: _____

Address 2: Room 205
 IL Zip: 61080
 State: _____
 Email: mbradley@lagpharma.com
 Fax: 815-824-7887

ADDITIONAL PRODUCT INFORMATION

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

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

If Unit Dose NDC, indicate NDC here: _____

Country of Origin: China _____

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

PRODUCT DESCRIPTION INFORMATION

Size: 1000

Strength: 500mg

Dosage Form: Tablet

Product Shape: Round

Product Color: White

Product Imprint: _____

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? Yes No

Is product exempt from DSCSA? Yes No

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

Is product repackaged? No Yes

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

GTIN PRODUCT INFORMATION

Item	Level	GTIN-14	Quantity
<input checked="" type="checkbox"/>	Case	00351224020702	
<input checked="" type="checkbox"/>	Box/Bundle/Inner Pack	30351224020703	
<input checked="" type="checkbox"/>	Pallet	50351224020707	
<input type="checkbox"/>	Case		
<input type="checkbox"/>	Box/Bundle/Inner Pack		
<input type="checkbox"/>	Pallet		

PHARMACY ORDER / BILL UNIT

Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

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

ORDER INFORMATION

Unit of Sale: Bottle Box/ Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Powder Multi Other: Write in _____

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: 6
 Inner/ Carton/ Pack:
 Case:

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US mmm.) Depth Height Width	Volume (Cube)	# Pieces:
Box/ Carton/ Bundle/ Inner Pack:	1.56	4.078 2.825		1
Case:	9.36			6
Pallet:	37.47	14.96 16.14 12.59		24
UPC:				

COST INFORMATION

Regular Cost Invoice Cost (WAC) (\$): _____
 Federal Excise Tax Per Unit of Sale: _____
 As of date: 7/5/2019

WHOLESALE USE ONLY:

Vendor #: _____
 What. Code #: \$47.70
 Finline Code: _____

Signature: _____

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.

*Please provide any additional information on page 2.

Melissa Bradley



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

Is this product regulated for shipment by DOT or IATA?

- 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:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- 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? No

If Yes, is it managed with a pharmacy registry?

Website URL:

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

REMS: No

REMS Program Manager Name:

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

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@tagpharma.com

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 #:

Name:

Phone:

Fax Number:

Fax Number:

Phone No.:

Site Address:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier:

Cut off time: 12:00pm Central

Shipping lead time of PO: Hours Days

Ships same day for next day receipt: No Yes

Ships for second day receipt: No Yes

Ships regular ground for 3-10 days receipt: No 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: No No

Drop Ship miscellaneous fees billed: No

Comments:

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:

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

Priority Overnight receipt available: Yes No

PO Receipt Cut off time: 12:00pm

Saturday Overnight receipt available: Yes No

PO Receipt Cut off time:

Order receipt method: Yes No

Phone: Phone #:

Fax: Fax #:

EDI:

Overnight Fees apply: Yes No

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

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:

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]:52LC50-72h-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 data sheets.

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