

# Standard Pharmaceutical Product Information (Rx Product Only)

						Introduction Type:	New Item		Final Version			Date:	6/27	72019
			PRODUCT INFORM	IATION		A			SPECIAL HANDL	ING AND STO	DRAGE REQ	UIREMENTS	10	
Company Name:	a. Temperature – Indicate the USP temperature range for this product.													
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(med device):		A205096	3			Tempe	rature Range		Controlled R	toom – betwe	en 20 and 25	C (68° – 77°
DUNS:								Other '	Temperature Range Re	equirement				
Proprietary Name (If Applicable) and Established Name: Metformin Hydrochloride Immediate-Release Tal								(	write in)					I
Selling Unit NDC:	51224-020-60		Individual Unit NDC			UPC: MVX Code:					:0		Ma	
UDI			GVX Code:			MVX Code:		= 1	product to be shipped t				No No	-
Description:	Metformin IR 500mg	500 count						Is this	product to be shipped t	to customers of	on dry ice?		No	-
Active Ingredient(s):	b, Contact for tempe	rature excursion que	stions:											
Active Ingredient(s): Metformin IR								Name:			Mat Mathis			
URL for Additional Product I								Numb			815-624-766	-		
Address:	722 Progressive Lane				Address 2: Room 205 State: IL Zip: 61080			Group	E-mail:		druginfo@ta	gipharma.co	m	
City:	South Beloit Melissa Bradley				Email: mbradley@tagipharma.com			c. Special regulation	s for product in any s	tates?			No	
Key Contact: Phone Number:	815-624-7685				Fax: 815-624-7687				I returns requirements		ct?		No	-
Product Therapeutic Classifi									•	•				-
d. Store product (unit of sale) upright?  Yes														_
ADDITIONA	IL PRODUCT INFORM	IATION			PRODU	UCT DESCRIPTION	INFORMATION	Protect product (unit of sale) from light?  Yes						=
Is the Product				1				e. Shelf life:				24	Months	
a legend device?	rice? No		Size	Size: 500 count			Initial	Initial shelf life at launch (If different):						
reverse numbered?		No No		1					ORDER INFORMATION					
co-licensed?		Direct-Ship Only		Stre	ngth:	500mg								
Is the Product		Neither		Dos	age Form:	Tablet		Unit of			What is the	NDC selling	unit?	
				500	ago i oinii	Tubiot		X			DATE: 1		010-6-1	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?					¬II	Box/Carton Ampule		(write-in, e.	g. 1 Box of 1	J Viais)		
If Unit Dose NDC, indicate NI	DC here			Proc	Product Shape: Round				Glass		Minimum o	rder quantity	17	Yes
II Olik Dood 1450, maloato 11	DO 11010.			Den.	luct Colors	White		111 ==	Tube					
Country of Origin China Product Color: White									Vial Liquid Sgl		1034			
Is this product covered under the Trade Agreements Act (TAA)?									Vial Liquid Multi Vial Powder Sql			many of wh	ich package 1	type?
No No								-11 -	Vial Power Multi		-	Inner/Cartor	√Pack	
				4					Other: Write In	_		Case		
			FOR GENERIC DRUG P	RODUCTB										
		_	DHAE	RMACY ORDE	D/RUI UN	T	_							
10 0 10 0			- L	Authorized Generic *If Authorized Generic, other section fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:				
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?:							THE STATE OF THE S	Otto T	1	rox binning o	Each	aoy.		
								(Write-in, e.g. 1 Vial)				Gram		
كالمستدينين		DRUG SUPPL	Y CHAIN SECURITY ACT	T (DSCSA) INFORM	ATION							Millititer		
			Yes	GLN:	_				ITEM A	ND PACKING	INFORMAT	ION		
Does supplier meet DSCSA of Is product exempt from DSC			No.	_ OLN.	_									
If yes, select exemption:									Weight Lbs.		nsions (US n		Volume	# Pieces:
Other exemption - Write in:								To the second se	Trongin Lines	Depth	Height	Width	(Cube)	
Is product repackaged?			No No	_ If Yes, w		duct purchased dire	ect	Item:	0.76		4.078	2 625		1
Is product sold by manufacts Has FDA granted waiver/exc			No	_		tation from FDA.		Box/Carton/Bundle/	450					8
Itas i six grantou marronono	- Parameter Parameter 1							Inner Pack:	4.56					0
			GTIN PRODUCT INFO					Case:	55.11	12.99	18.89	18.89		72
			Level	Saleable Unit		Quai	ntity GTIN-14	Pallet:		-				-
Serialized?	Ves	. х	Item		2D -	Lineer Coulan	00351224020603							
If not, when?	103		Box/Carton/Bundle/Inner Pack		_	K Linear	30351224020604	UPC:	Case:					
Items aggregated?	ms aggregated?							Carton:						
	Pallet 20 Linear						COST INFORMATION WHOLESALER USE ONLY:							
				1	2D 2D	Linear		- 003	THE OTHER HOIL			- THO SECOND	EN OOL OIL	
					2D	Linear		Regular Cost			Vendor#:			
					2D	Linear		Invoice Cost (WAC)		\$26.10	Whal. Code			
								Federal Excise Tax F As of date:	Per Unit of Sale 7/5/2019	_	Fineline Co	de:		
								As of date:	770/2018		1			
		Α.	ttach copy of SAFFTY D	ATA SHEET (SDS)	or non hazard lett	ter. PACKAGE INSE	RT, LABEL AND PHOTO OF F	PRODUCT PACKAGING and	BARCODE.					
*Places provide any addition	al information on par						nated Drop Ship Only.	Signat				Meliss	a 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): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Corrosive Is the product a CA Prop 65 carcinogen? No Organic Oxidizer Is the product a CA Prop 65 reproductive toxicant? No Inorganic Contact Hazard Does the product label bear a CA Prop 65 warning? No Steroid/Androgen c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No Is the product a NIOSH hazardous drug? (If yes, attach SDS with special instructions.) If yes, indicate which: e. Does the product contain DEHP? No No Is this product regulated for shipment by DOT or IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: No Is there a REMS on this product? Passenger If Yes, is it managed with a pharmacy registry? Cargo Website URL: Passenger & Cargo Is this a reportable quantity? No Comments / Details: (For example, iPledge program?) RQ Threshold: No Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS Program Manager Name: Phone: Limited Quantity Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Wholesale distributor support: Small Quantity (49 CFR 173.4) Provider Name: Special Permit; DOT-SP Site Enrollment Number assigned DEA #: Special Provision (listed in Column 7 of 49 CFR 172.101); PCPDP# by Supplier: SP# ADD'L STORAGE INFORMATION Comments Is the Product... Νo Controlled Substance? Controlled by State(s)? No Registry: Registry Program Contact Name: Phone: ARCOS Reportable? No Comments Schedule No. (inc. N for non-narcotic) Controlled Substance Code RETURN INSTRUCTIONS No Listed Chemical (List I or II) If yes, indicate which: 855-225-8244 Contact tel. # if product received damaged: No Is it a scheduled listed chemical product?: Yes CLASS OF TRADE RESTRICTION: Is product returnable for credit: URL/Link to returns policy: Yes No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Special regulations or returns requirements for this product in certain states? No Restricted to retail pharmacy only: No If so, which states? Other requirements? Comments? Restricted to hospital, clinics, and physician offices only: Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or email: customercare@tagipharma.com No Restricted from US territories? (explain in comments) Comments: 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.

FUR DESIGNATED DROP SHIP PRODUCT ONLY - II	Standard Order Receipt and Processing
Order Method for Designated Drop Ship Product	
Purchase orders may be accepted by:  a. EDI Yes	Purchase order daily receipt cut off time by supplier  Cut off time: 12:00pm Central
b. Autofax Yes Fax Number: 815-624-7687 c. Fax Yes Fax Number: 815-624-7687 d. Phone only Phone No.: 855-225-8244	Shipping lead time of PO: Hours Days
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt:  Ships for second day receipt:  No
Minimum Order Quantity: Supplier's Customer Service Number: 855-225-8244	Ships regular ground for 3-10 days receipt:  Yes
Supplier's Customer Service Number: 855-225-8244  Contracted 3PL company / contact #: Name:	Onips regular ground for a 10 days recorpt.
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Yes	Overnight receipt available: Yes
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 12:00pm Central
Drop Ship miscellaneous fees billed: No Comments:	Days of week overnight is available:   x  Monday  Tuesday  Wednesday  Thursday  Friday
	Priority Overnight receipt available: Yes
Class of Trade Restriction:	PO Receipt Cut off time: 12:00pm
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No Comments:	Saturday Overnight receipt available:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	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
	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, maycause 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 allergicreaction. 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 andwater, 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 advice and all 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 dioxideand 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 withrespiratory 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 andclothing. 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. Keepcontainer 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:C4H12CIN5Molecular 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 mayinduce 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 aquaticenvironment.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 collectionpoint. Dispose in a safe manner in accordance with local/national regulations.

CSPC OUYI PHARMACEUTICAL CO.,LID.

石药集团欧意药业有限公司

#### 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 theaquatic 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 theaquatic environment.

**EXPIRY DATE: 01/24/2018**