



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: <input type="checkbox"/> Final Version <input checked="" type="checkbox"/> New Item	Date: 6/27/2019	SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name: Targi Pharma, Inc. Application Number for NDA/ANDA/BLA (drug): PMA1510(k)(med device): A205008 Application: ANDA		a. Temperature - Indicate the USP Temperature range for this product. Controlled Room - between 20 and 25 C (68° - 77° F) Temperature Range: _____ Other Temperature Range Requirement (write in): _____	
DUNS: _____ Proprietary Name (if applicable) and Established Name: Mefloquine Hydrochloride Immediate-Release Tablets, USP Selling Unit NDC: 51224-120-60 Individual Unit NDC: _____ UDI: _____ CVA Code: _____ MYX Code: _____ Description: Mefloquine IR 850mg 500 count		b. Contact for temperature excursion questions: Name: Mat Mehlis Number: 815-624-7685 Group E-mail: druginfo@targipharma.com	
Active Ingredient(s): Mefloquine IR URL for Additional Product Information: www.targipharma.com Address: 722 Progressive Lane City: South Bolton Key Contact: Melissa Bradley Phone Number: 815-624-7685 Product Therapeutic Classification: _____		c. Special regulations for product in any states? Special returns requirements for this product? No d. Store product (unit of sale) upright? Yes Protect product (unit of sale) from light? Yes e. Shelf life: Initial shelf life at launch (if different): 24 Months	
ORDER INFORMATION			
Unit of Sale: <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/ Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> 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 _____ Inner/ Carton/ Pack _____ Case _____	
PHARMACY ORDER / BILL UNIT			
Rec. sell unit to customer? _____ (Write-in, e.g. 1 Vial) _____		Rx billing unit to pharmacy: Each _____ Gram _____ Milliliter _____	
ITEM AND PACKING INFORMATION			
Item:	Weight Lbs.	Dimensions (US ments) Depth Height Width	Volume Volume (Cube)
Box/ Carton/ Bundle/ Inner Pack:	1.37 8.22	4.078 2.625	1 6
Case:	33.08	14.96 16.14 12.59	24
Pallet:			
UPC:	Case: Carton:		
COST INFORMATION			
Regular Cost	Vendor #:	Wholesaler USE ONLY:	
Invoice Cost (WAC) (\$)	\$34.52	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date: 7/5/2019			

PRODUCT DESCRIPTION INFORMATION	
Size: 500	Strength: 850mg
Dosage Form: Tablet	Product Shape: Round
Product Color: White	Product Imprint:

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device? <input type="checkbox"/> No reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No Is the Product... Direct-SHIP Only? <input type="checkbox"/> No Neither? <input type="checkbox"/> No	If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No If Unit Dose NDC, indicate NDC here: _____ Country of Origin: China Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: _____	Authorized Generic: <input type="checkbox"/> Authorized Generic, other section fields are not applicable

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> No Is product exempt from DSCSA? <input type="checkbox"/> No If yes, select exemption: Other exemption - Write in: _____ Is product repackaged? <input type="checkbox"/> No Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No Has FDA granted waiver/exemption/exemption for product? <input type="checkbox"/> No	GLN: _____ If Yes, was original product purchased direct from mfr? <input type="checkbox"/> No If yes, attach documentation from FDA.

GTIN PRODUCT INFORMATION	
Serialized? <input checked="" type="checkbox"/> Yes If not, when? _____ Items aggregated? <input type="checkbox"/> No	Item: <input checked="" type="checkbox"/> X Box/ Carton/ Bundle/ Inner Pack: <input checked="" type="checkbox"/> X Case: <input checked="" type="checkbox"/> X Pallet: <input type="checkbox"/>
Level: _____ Schedule Unit: _____	Quantity: _____ GTIN-14: 50351224120600 50351224120601 50351224120605

*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.

Signature: 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? No
Is the product a CA Prop 65 reproductive toxicant? No
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.) No

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? No

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? (if yes, identify method below)

Limited Quantity No

Consumer Commodity, ORM-D No

Small Quantity (49 CFR 173.4) No

Special Permit, DOT-SP No

Special Provision (listed in Column 7 of 49 CFR 172.101):

SP#

ADD'L STORAGE INFORMATION

Is the Product... No

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 Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Aerosol Class: Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

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? No

Website URL:

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

REMS: No Yes

REMS Program Manager Name:

Supplier Manages REMS registry exclusively: No Yes

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Phone:

Comments

Registry: No Yes

Registry Program Contact Name:

Phone:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

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: customercare@legpharma.com

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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: 855-225-8244

Contracted 3PL company / contact #: _____

Name: _____

Phone: _____

Fax Number: 815-624-7687

Phone No.: 815-624-7687

Site Address: 855-225-8244

Standard Order Receipt and Processing

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

Cut off time: _____

Shipping lead time of PO: _____ Hours _____ Days

Ships same day for next day receipt: No

Ships for second day receipt: No

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 No

Drop Ship service fee billed with each order: Yes No

Drop Ship miscellaneous fees billed: Yes 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

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: Yes No

Restricted to hospital, clinics, and physician offices only: Yes No

Restricted from US territories? (explain in comments) Yes No

Comments: _____

Saturday Overnight receipt available:

PO Receipt Cut off time: Yes No

Phone #: 855-225-8244

Fax #: 815-624-7687

EDI: _____

Overnight Fees apply: Yes No

Other fees apply: _____

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: _____

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 collectionpoint.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