Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020 | Introduction Type: Post Launch Change | x Final Version | Date: 8/23/2023

PRODUCT INFORMATION

Company Name:	Viona Pharmaceuticals Inc.			Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	077078				
DUNS:	081468959				
Proprietary Name (If Applicable) and Established Name:					
Selling Unit NDC:	72578-036-01	Unit of Use NDC:		UPC:	372578136010
UDI	N/A	CVX Code:		MVX Code:	N/A
Description:	White to off-white, capsule shaped, uncoated tablets, debossed with "Z", "C" on one side and "20" on the other side.				
Active Ingredient(s):	Metformin Hydrochloride, USP				
URL for Additional Product Information:	www.vionausa.com				
Address:	20 Commerce Drive	Address 2:	Suite 340		
City:	Cranford	State:	NJ	Zip:	07016
Key Contact:	Chris Urbanski	Email:	Curbanski@vionausa.com		
Phone Number:	908-956-0600	Fax:	908-514-4005		
Product Therapeutic Classification:	Antihyperglycemic Agent				

ADDITIONAL PRODUCT INFORMATION

The product is?		Is the Product…	Direct-Ship Only
a legend device?	No	Is the Product…	Neither
if yes, enter class #		Orphan Drug Status	
a product kit?	No		
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	No		
co-licensed?	No	Allergens Present	
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No	Country of Origin	India
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:		Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	100 count
Strength:	750 mg
Dosage Form:	Extended-Release Tablet
Product Shape:	Capsule
Product Color:	White to Off-White
Product Imprint:	"Z" "C"; "20"

FOR GENERIC DRUG PRODUCTS

			Authorized Generic
I. Orange Book Rating:	AB	*If Authorized Generic, other section fields are not applicable	
II. Generic Equivalent to What Brand?:	Glucophage XR		

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	0372578000004
Is product exempt from DSCSA?	No		
If yes, select exemption:			
Other exemption - Write in:			
Is product repackaged?	No	If Yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	No		
Has FDA granted waiver/exception/exemption for product?	No	If yes, attach documentation from FDA.	

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00372578036010	
	Box/Carton/Bundle/Inner Pack				
x	Case	24		40372578036018	
x	Pallet	1,440		50372578036015	

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)	
Notes	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No

b. Contact for temperature excursion questions:

Name:	Customer Service
Number:	888-304-5022
Group E-mail:	customerservice@vionausa.com

c. Special regulations for product in any states?	No	
Special returns requirements for this product?		
d. Store product (unit of sale) upright?	Yes	
Protect product (unit of sale) from light?	Yes	
e. Shelf life:	24	Months
Initial shelf life at launch (if different):		Months

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?	
1	Bottle	1 Bottle of 100 Tablets	
	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)	
	Ampule		
	Glass	Minimum order quantity?	Yes
	Tube		
	Vial Liquid Sgl		
	Vial Liquid Multi	If Yes, how many of which package type?	
	Vial Powder Sql	24	Each
	Vial Power Multi		Inner/Carton/Pack
	Other: Write In	1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?		Rx billing unit to pharmacy:	
1 Bottle		x	Each
(Write-in, e.g. 1 Vial)			Gram
			Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	# Pieces:
Item/Each:	0.32	2.45	2.45	4.3		1
Box/Carton/Bundle/ Inner Pack:						
Case:	9.63	14.72	9.69	5.24		24
Pallet:	595.15	47.24	39.37	49.21		1,440

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	
As of date:	

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

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. See new p. 3 for Designated Drop Ship Only. Signature:

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Version 2020

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? No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? No

(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 this product regulated for shipment by IATA? No

(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?

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?

No (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#

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:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required No

Limited Distribution Requirement No

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

REMS:

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: PCPDP#: NPI #:

Comments

Registry:

Registry Program Contact Name: Phone:

Comments

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance? No — Controlled Substance Code

Controlled by State(s)? No — Listed Chemical (List I or II)

ARCOS Reportable? No — If yes, indicate which:

Schedule No. — Is it a scheduled listed chemical product?:

CLASS OF TRADE RESTRICTION:

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)

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 888-304-5022

Is product returnable for credit: Yes

URL/Link to returns policy: www.vionausa.com

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

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

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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
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: 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
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:
PO Receipt Cut off time:

Saturday Overnight receipt available:
PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

Class of Trade Restriction:

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)
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:

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?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?