



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

Version 2020

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	Modavar Pharmaceuticals LLC (U.S. Agent for Cadila Pharmaceuticals Limited)		Application: ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	203379		
DUNS:	858949204		
Proprietary Name (if Applicable) and Established Name:	Glyburide Tablets, USP 1.25mg		
Selling Unit NDC:	7224103805	Unit of Use NDC:	
UDI		UPC:	372241038051
		CVX Code:	
		MX Code:	
Description:	Glyburide Tablets, USP 1.25mg 100s		
Active Ingredient(s):	Glyburide 1.25mg		
URL for Additional Product Information:	www.modavar.com		
Address:	1016 16th St., NW, Suite 602	Address 2:	
City:	Washington	State:	DC
		Zip:	20036
Key Contact:	Lewis "Lew" Soars	Email:	Lewis@Modavar.com
Phone Number:	(202) 868-2391	Fax:	(202)355-9784
Product Therapeutic Classification:	ANTIDIABETIC		

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?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
b. Contact for temperature excursion questions:	
Name:	Customer Service
Number:	800-688-4697
Group E-mail:	ModavarCS@Eversana.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device?	<input type="checkbox"/> No	Is the Product... Direct And Drop-Ship	<input type="checkbox"/> Neither
if yes, enter class # a product kit?	<input type="text"/>	Orphan Drug Status	<input type="checkbox"/>
if yes, list NDCs of component parts	<input type="text"/>	FDA Approval Status	<input type="text"/>
reverse numbered?	<input type="checkbox"/> No	Allergens Present	See Package Insert - patient specific
co-licensed?	<input type="checkbox"/> No	Country of Origin	India
latex-free?	<input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
preservative-free?	<input type="checkbox"/> Yes		
correctional institution block?	<input type="checkbox"/> No		
opioid?	<input type="checkbox"/> No		
Cannabinoid?	<input type="checkbox"/> No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
		Size:	100 ct bottle
		Strength:	1.25mg
		Dosage Form:	Tablet
		Product Shape:	Round, biconvex
		Product Color:	white to off-white
		Product Imprint:	'C13' on one side; horizontal bisect on other

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 bottle of 100 tablets
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text" value="x"/> Inner/Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text"/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB1
II. Generic Equivalent to What Brand?:	Micronase®
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1"/> pill	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION		
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes	GLN: 372241000003
Is product exempt from DSCSA?	<input type="checkbox"/> No	
If yes, select exemption:	<input type="text"/>	
Other exemption - Write in:	<input type="text"/>	
Is product repackaged?	<input type="checkbox"/> No	If Yes, was original product purchased direct from mfr?
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No	If yes, attach documentation from FDA.
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.63934	1.5365433	1.5365433	2.7559	6.5065843	1
Box/Carton/Bundle/Inner Pack:	2.205	9.69	6.38	3.5433	219.0546	24
Case:	14.8	13.78	10.67	11.811	1736.602	144
Pallet:	463.05	47.24	39.37	47.24	87858.785	4320

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00372241038051	NOS
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	24		20372241038055	
<input checked="" type="checkbox"/> Case	144		40372241038059	
<input checked="" type="checkbox"/> Pallet	4320		50372241038056	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$12.60	Whsl. Code #:	
As of date:	2/24/2022	Fineline Code:	

*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:

Lew Soars



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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? No
 - 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?

- (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?

- (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:

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#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? No Controlled Substance Code
- Controlled by State(s)? No Listed Chemical (List I or II) No
- ARCOS Reportable? No If yes, indicate which:
- Schedule No. 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? No
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: No
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: No
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 800-688-4697

Is product returnable for credit: Yes
URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No
If so, which states? Other requirements? Comments?

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	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="checkbox"/> Drop Ship service fee billed with each order: <input type="checkbox"/> Drop Ship miscellaneous fees billed: <input type="checkbox"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="checkbox"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="checkbox"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	Return Instructions
<input type="text"/>	<input type="text"/>
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>