HDA

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

Version 2020

Introduction Type:	New Item		x	Final Version	Date:	2/7/2022

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):	208717
DUNS:	858949204
Proprietary Name (If Applicable) and Established Name:	Nebivolol Tablets, 2.5mg
Selling Unit NDC:	72241-032-22
Unit of Use NDC:	
UPC:	372241032226
UDI	
CVX Code:	
MVX Code:	
Description:	Nebivolol Tablets, 2.5mg 30s
Active Ingredient(s):	Nebivolol 2.5mg
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:	ANTIHYPERTENSIVE

ADDITIONAL PRODUCT INFORMATION

The product is?	
a legend device?	No
if yes, enter class #	
a product kit?	No
if yes, list NDCs of component parts	
reverse numbered?	No
co-licensed?	No
latex-free?	Yes
preservative-free?	Yes
correctional institution block?	No
opioid?	No
Cannabinoid?	No
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose, indicate NDC here:	

Is the Product…	Direct And Drop-Ship
Is the Product…	Neither
Orphan Drug Status	
FDA Approval Status	
Allergens Present	See Package Insert - patient specific
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	30 ct bottle
Strength:	2.5mg
Dosage Form:	Tablet
Product Shape:	Round, biconvex
Product Color:	white to off white
Product Imprint:	debossed 'C50' one side; plain on other

FOR GENERIC DRUG PRODUCTS

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

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes
GLN:	372241000003
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		00372241032226	NOS
x	Box/Carton/Bundle/Inner Pack	24		20372241032220	
x	Case	96		40372241032224	
x	Pallet	3072		50372241032221	

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:	800-688-4697
Group E-mail:	ModavarCS@Eversana.com

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

ORDER INFORMATION

Unit of Sale		
X	Bottle	
	Box/Carton	
	Ampule	
	Glass	
	Tube	
	Vial Liquid Sgl	
	Vial Liquid Multi	
	Vial Powder Sgl	
	Vial Power Multi	
	Other: Write In	

What is the NDC selling unit?	1 bottle of 30 tablets
	(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity?	Yes
If Yes, how many of which package type?	
24	Each
x	Inner/Carton/Pack
	Case

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.055	1.575	1.575	2.953	7.3237646	1
Box/Carton/Bundle/Inner Pack:	2.701	11.02	7.402	4.331	353.27984	24
Case:	10.8045	16.54	12.60	10.24	2132.41	96
Pallet:	372.204	47.244	39.37	47.244	87873.664	3072

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$6.95
As of date:	2/7/2022

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: _Lew Soars_

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

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? — 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#

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   PCPDP#:
- by Supplier: NPI #:
- Comments

Registry: — No
- 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) — 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:

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:

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	Standard Order Receipt and Processing