



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):	208717		
DUNS:	858949204		
Proprietary Name (if Applicable) and Established Name:	Nebivolol Tablets, 20mg		
Selling Unit NDC:	72241-035-04	Unit of Use NDC:	
UDI		UPC:	372241035043
		CVX Code:	
		MXV Code:	
Description:	Nebivolol Tablets, 20mg 90s		
Active Ingredient(s):	Nebivolol 20mg		
URL for Additional Product Information:	www.modavar.com		
Address:	1016 16th St., NW, Suite 602	Address 2:	
City:	Washington	State:	DC
Key Contact:	Lewis "Lew" Soars	Zip:	20036
Phone Number:	(202) 868-2391	Email:	Lewis@Modavar.com
		Fax:	(202)355-9784
Product Therapeutic Classification:	ANTIHYPERTENSIVE		

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	
if yes, enter class #		Is the Product... Orphan Drug Status	<input type="checkbox"/> Neither
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	<input type="checkbox"/> No	Allergens Present	See Package Insert - patient specific
co-licensed?	<input type="checkbox"/> No	Country of Origin	<input type="text" value="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:			
		Size:	90 ct bottle
		Strength:	20mg
		Dosage Form:	Tablet
		Product Shape:	Round, biconvex
		Product Color:	white to off white
		Product Imprint:	debossed 'C53' one side; plain on other

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 bottle of 90 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 checked="" type="checkbox"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/>

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

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: <input type="text" value="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? <input type="checkbox"/>
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:	0.143	1.575	1.575	3.031	7.5190648	1
Box/ Carton/ Bundle/ Inner Pack:	4.851	11.1	5.78	4.33	277.80414	24
Case:	19.404	16.54	12.60	10.24	2132.4137	96
Pallet:	678.66	47.244	39.37	47.244	87873.664	3072

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		00372241035043	<input type="text" value="NOS"/>
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	24		20372241035047	
<input checked="" type="checkbox"/> Case	96		40372241035041	
<input checked="" type="checkbox"/> Pallet	3072		50372241035048	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$19.95	Whsl. Code #:	
As of date:	2/7/2022	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													
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? No</p> <p>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</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No</p> <p>e. Does the product contain DEHP? No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="border: none;"><input type="checkbox"/> Organic</td> <td style="border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="border: none; padding-top: 5px;"> <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/> </td> </tr> <tr> <td colspan="2" style="border: none; padding-top: 5px;"> Is the product a NIOSH hazardous drug? No If yes, indicate which: <input type="text"/> </td> </tr> </table> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">Hazardous Waste Identification</p> <table style="width: 100%; border: none;"> <tr> <td style="border: none; padding: 2px;">EPA Hazardous Waste Code: <input type="text"/></td> <td style="border: none; padding: 2px;">Waste Characteristics: <input type="text"/></td> </tr> </table> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; background-color: #003366; color: white; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? No</p> <p>If Yes, is it managed with a pharmacy registry? <input type="text"/></p> <p>Website URL: <input type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> PCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry: No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p> </div>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard	<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/>		Is the product a NIOSH hazardous drug? No If yes, indicate which: <input type="text"/>		EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics: <input type="text"/>
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EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics: <input type="text"/>												
ADD'L STORAGE INFORMATION													
<p>Is the Product...</p> <p>Controlled Substance? No Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? No Listed Chemical (List I or II) No</p> <p>ARCOS Reportable? No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product?: No</p>													
CLASS OF TRADE RESTRICTION:													
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes</p> <p>Restricted to retail pharmacy only: No</p> <p>Restricted to hospital, clinics, and physician offices only: No</p> <p>Restricted from US territories? (explain in comments) No</p> <p>Comments: <input type="text"/></p>													
RETURN INSTRUCTIONS													
<p>Contact tel. # if product received damaged: <input type="text" value="800-688-4697"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>													
MISCELLANEOUS NOTES and/or Image of Product Barcode:													
<input type="text"/>													

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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
	
	
	
	
	