

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

Version 2020				Introduction Type:	New Item	х	Final Version		Date:	2/7/	2022		
		PRODUCT INFORMA	TION				SPECIAL HANDLING AND	STORAGE REQU	REMENTS*				
Company Name: Modavar Pharmaceuticals LLC (U.S. Agent for Cadila Pharmaceuticals Limited) Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.							
	DA/ANDA/BLA (drug); PMA/510(k)(med device): 208717						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS:		858949204				Other To	emperature Range Requirement						
Proprietary Name (If Applicable) a	and Established Name:	Nebivolol Tablets, 10mg				1	rite in)						
Selling Unit NDC:	72241-034-04	Unit of Use NDC:		UPC: 37224	1034046	Notes	,						
UDI		CVX Code:		MVX Code:									
Description:	Nebivolol Tablets, 10mg 9	ne .				le this n	roduct to be shipped to custome	rs on ice?		No			
2000	respire of rapide, rong o					11	roduct to be shipped to custome			No	-		
Active Ingredient(s):	Nebivo	olol 10mg				1					-		
						b. Contact for tempera	ature excursion questions:						
URL for Additional Product Inform	nation: www	.modavar.com				Name:		Customer S	ervice				
Address:	1016 16th St., NW, Suite 6					Number: 800-688-4697							
City:	Washington		20036	Group E-mail: ModavarCS@Eversana.com									
Key Contact: Phone Number:	Lewis "Lew" Soars (202) 868-2391		Email Fax:		<u>m</u>	Special regulations	for product in any states?			No			
Product Therapeutic Classification		YPERTENSIVE	I da.	(202)333-9764		<u> </u>		duat?		No No	-		
Product Therapeutic Classification	n: ANTIN	TPERTENSIVE				Special	returns requirements for this pro	duct?		INO	-		
	ADDITIONAL PE	RODUCT INFORMATION		PRODUCT DESCR	RIPTION INFORMATION	d. Store product (unit	of sale) unright?			No			
The mys dust is 2	ABBITIONALTIN		Direct And Deep Ob	T NODOOT DESCI	- ION IN ONINATION	7 I		-42			-		
The product is? a legend device?	NI-	Is the Product Is the Product	Direct And Drop-Ship		90 ct bottle	e. Shelf life:	product (unit of sale) from lig	ntr		No 24	Months		
if yes, enter class #	No	Orphan Drug Status	Neither	Size:	50 of bottle		helf life at launch (if different):			24	Months		
a product kit?	No	C.p.ian Drug Glatus		0	10mg		(11 4111016111).				1		
if yes, list NDCs of		FDA Approval Status		Strength:			ORDER IN	IFORMATION					
component parts				Dosage Form:	Tablet								
reverse numbered?	No	<u> </u>		Dosage i oiiii.		Unit of			NDC selling	unit?			
co-licensed?	No	Allergens Present				Х	Bottle	1 bottle of 3					
latex-free?	Yes	See Package Inser	rt - patient specific	Product Shape:	Round, biconvex		Box/Carton	(Write-in, e	.g. 1 Box of 1	0 Vials)			
preservative-free? correctional institution block?	Yes				white to off white		Ampule Glass	Minimum	rder quantit	,2	Voc		
opioid?	No No	_		Product Color:	writte to oil writte		Tube	William	ruer quantit	y :	Yes		
Cannabinoid?	No No	Country of Origin	India		debossed 'C52' one side;		Vial Liquid Sgl						
If Unit Dose, is item bar coded to u				Product Imprint:	plain on other		Vial Liquid Multi	If Yes, how	many of wh	ich package	type?		
scanning?	· ·	Is this product covered u	under the				Vial Powder Sql	24	Each				
If Unit Dose, indicate NDC here:		Trade Agreements Act (1	TAA)? No				Vial Power Multi	x	Inner/Cartor	/Pack			
						IJ <u> </u>	Other: Write In		Case				
		FOR GENERIC DRUG PR	ODUCTS										
						PHARMACY ORDER / BILL UNIT							
			_		norized Generic, other section			RDER / BILL UNIT					
I. Orange Book Rating:	AB		A		norized Generic, other section are not applicable	Rec. sell unit to custo	mer?		nit to pharm	асу:			
I. Orange Book Rating: II. Generic Equivalent to What Bra		78	A			Rec. sell unit to custo	mer?		Each	acy:			
	and?: Bystoli					Rec. sell unit to custo	mer?		Each Gram	acy:			
	and?: Bystoli	⊙® RUG SUPPLY CHAIN SECURITY ACT (Rec. sell unit to custo	mer?		Each	acy:			
II. Generic Equivalent to What Bra	Bystoli			fields a		Rec. sell unit to custo	omer?		Each Gram Milliliter	acy:			
	Bystoli	RUG SUPPLY CHAIN SECURITY ACT ((DSCSA) INFORMATION			Rec. sell unit to custo	omer?	Rx billing u	Each Gram Milliliter	acy:			
II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA?	Bystoli	RUG SUPPLY CHAIN SECURITY ACT ((DSCSA) INFORMATION	fields a		Rec. sell unit to custo	OMER?	Rx billing u	Each Gram Milliliter				
II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption:	Bystoli	RUG SUPPLY CHAIN SECURITY ACT ((DSCSA) INFORMATION	fields a		Rec. sell unit to custo	omer? II ITEM AND PACE Weight Lbs.	Rx billing to x X XING INFORMATIO mensions (US msi	Each Gram Milliliter	Volume (Cube)	# Pieces:		
II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA?	Bystoli	RUG SUPPLY CHAIN SECURITY ACT ((DSCSA) INFORMATION GLN:	fields a		Rec. sell unit to custo	omer? II ITEM AND PACE Weight Lbs. Dept	Rx billing u x ING INFORMATIO mensions (US msi	Each Gram Milliliter N nts.)	Volume (Cube)			
II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	DR	RUG SUPPLY CHAIN SECURITY ACT (Yes No	(DSCSA) INFORMATION GLN:	fields a 372241000003		Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial)	omer? II ITEM AND PACE Weight Lbs.	Rx billing u x ING INFORMATIO mensions (US msi	Each Gram Milliliter	Volume	#Pieces:		
II. Generic Equivalent to What Branch II. Generic Equivalent to What Branch II. Broduct exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	ition of manufacturer?	Yes No No No	(DSCSA) INFORMATION GLN: If Yes, was ordirect from more and the second	fields a 372241000003		Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/	Weight Lbs. Di Depti	Rx billing u x KING INFORMATIO mensions (US msi h Width 5 1.575	Each Gram Milliliter N nts.) Height 3.035	Volume (Cube) 7.527658	1		
Does supplier meet DSCSA defining product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	ition of manufacturer?	Yes	(DSCSA) INFORMATION GLN: If Yes, was or direct from m If yes, attach	fields a 372241000003 372241000003 riginal product purchased off?		Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack:	omer? II ITEM AND PACE Weight Lbs. Dept	Rx billing u x KING INFORMATIO mensions (US msi h Width 5 1.575	Each Gram Milliliter N nts.)	Volume (Cube)			
Does supplier meet DSCSA defining product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	ition of manufacturer?	Yes No No No	(DSCSA) INFORMATION GLN: If Yes, was or direct from m If yes, attach	fields a 372241000003 372241000003 riginal product purchased off?		Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/	Weight Lbs. Di Depti	Rx billing u x KING INFORMATIO mensions (US msi h Width 5 1.575 2 7.4	Each Gram Milliliter N nts.) Height 3.035	Volume (Cube) 7.527658	1		
II. Generic Equivalent to What Brazella Communication of the Inc.	ition of manufacturer? s exclusive distributor? n/exemption for product?	NO NO NO NO O O O O O O O O	(DSCSA) INFORMATION GLN: If Yes, was ordirect from many of yes, attach	372241000003 riginal product purchased offr? documentation from FDA.	are not applicable	Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	ITEM AND PACE Weight Lbs. Di Depti 0.093 1.578 3.528 11.02	Rx billing u x KING INFORMATIO mensions (US msi h Width 5 1.575 2 7.4	Each Gram Milliliter N Ints.) Height 3.035 4.33	Volume (Cube) 7.527658 353.10284	1 24		
II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	ition of manufacturer?	NO NO NO NO O O O O O O O O	(DSCSA) INFORMATION GLN: If Yes, was ordirect from more of the second	fields a 372241000003 riginal product purchased fir? documentation from FDA.	Unit of Use GTIN-14	Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack:	ITEM AND PACE Weight Lbs. Di Depti 0.093 1.578 3.528 11.02	Rx billing u x KING INFORMATIO mensions (US msi h Width 5 1.575 2 7.4 4 12.60	Each Gram Milliliter N Ints.) Height 3.035 4.33	Volume (Cube) 7.527658 353.10284	1 24		
II. Generic Equivalent to What Brack Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure	DR ition of manufacturer? s exclusive distributor? n/exemption for product? Quanti	NO NO NO NO OTIN AND HIBCC THE COMMON TO THE COMMON T	(DSCSA) INFORMATION GLN: If Yes, was or direct from m If yes, attach INFORMATION GT 000	fields a 372241000003 riginal product purchased fir? documentation from FDA.	are not applicable	Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	ITEM AND PACE	Rx billing u x KING INFORMATIO mensions (US msi h Width 5 1.575 2 7.4 4 12.60	Each Gram Milliliter N nts.) Height 3.035 4.33	Volume (Cube) 7.527658 353.10284 2132.4137	1 24 96		
II. Generic Equivalent to What Brack Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure	ition of manufacturer? s exclusive distributor? n/exemption for product?	NO NO OTIN AND HIBCC PRODUCT IN HIBCC	(DSCSA) INFORMATION GLN: If Yes, was or direct from m If yes, attach INFORMATION GT 000 200	fields a 372241000003 riginal product purchased fir? documentation from FDA.	Unit of Use GTIN-14	Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	ITEM AND PACE	Rx billing u x XING INFORMATIO mensions (US ms Midth 5 1.575 2 7.4 12.60 4 39.37	Each Gram Milliliter N nts.) Height 3.035 4.33 10.24 47.24	Volume (Cube) 7.527658 353.10284 2132.4137	1 24 96 3072		
II. Generic Equivalent to What Bra Does supplier meet DSCSA definite product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure X	ition of manufacturer? s exclusive distributor? n/exemption for product? Quantit 1 24	NO NO OTIN AND HIBCC PRODUCT II Tyes NO HIBCC	(DSCSA) INFORMATION GLN: If Yes, was ordirect from mild yes, attach INFORMATION GT 000 2000 400 400	riginal product purchased fir? documentation from FDA.	Unit of Use GTIN-14	Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	ITEM AND PACE	Rx billing u x XING INFORMATIO mensions (US ms Midth 5 1.575 2 7.4 12.60 4 39.37	Each Gram Milliliter N nts.) Height 3.035 4.33 10.24 47.24	Volume (Cube) 7.527658 353.10284 2132.4137 87873.664	1 24 96 3072		
II. Generic Equivalent to What Brazella Case Does supplier meet DSCSA definite product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure X	s exclusive distributor? n/exemption for product?	NO NO OTIN AND HIBCC PRODUCT II Tyes NO HIBCC	(DSCSA) INFORMATION GLN: If Yes, was ordirect from mild yes, attach INFORMATION GT 000 2000 400 400	372241000003 ariginal product purchased off? documentation from FDA. TIN-14 372241034046 3722241034040 3722241034044	Unit of Use GTIN-14	Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: Cos Regular Cost	ITEM AND PACE	Rx billing u x	Each Gram Milliliter N nts.) Height 3.035 4.33 10.24 47.24 WHOLESAL	Volume (Cube) 7.527658 353.10284 2132.4137 87873.664	1 24 96 3072		
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II. Generic Equivalent to What Brazella Case Does supplier meet DSCSA definition from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack Case	s exclusive distributor? n/exemption for product?	No No No STIN AND HIBCC PRODUCT II Ty HIBCC	If Yes, was or direct from m If yes, attach INFORMATION GT O00 200 400	772241000003 riginal product purchased fir? documentation from FDA. IN-14 372241034046 372241034040 372241034044 3722241034041	Unit of Use GTIN-14	Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: Cost Regular Cost Invoice Cost (WAC) (\$ As of date:	ITEM AND PACK Weight Lbs. Di	Rx billing u x	Each Gram Milliliter N Ints.) Height 3.035 4.33 10.24 47.24 WHOLESAL #: de:	Volume (Cube) 7.527658 353.10284 2132.4137 87873.664	1 24 96 3072		
II. Generic Equivalent to What Brazella Case Does supplier meet DSCSA definition from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure X Item/Each X Box/Carton/Bundle/Inner Pack Case	s exclusive distributor? n/exemption for product? Quanti 1 24 96 307	No No No STIN AND HIBCC PRODUCT II Ty HIBCC	If Yes, was or direct from m If yes, attach INFORMATION GT O00 200 400	772241000003 riginal product purchased fir? documentation from FDA. IN-14 372241034046 372241034040 372241034044 3722241034041	Unit of Use GTIN-14 NOS	Rec. sell unit to custo 1 pii (Write-in, e.g. 1 Vial) Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: Cost Regular Cost Invoice Cost (WAC) (\$ As of date:	ITEM AND PACE	Rx billing u x	Each Gram Milliliter N Ints.) Height 3.035 4.33 10.24 47.24 WHOLESAL #: de:	Volume (Cube) 7.527658 353.10284 2132.4137 87873.664	1 24 96 3072		



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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): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive No Oxidizer Is the product a CA Prop 65 reproductive toxicant? Inorganic Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard Aerosol Class; Identify NFPA Storage Level: c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? If yes, indicate which: No Is this product regulated for shipment by DOT? No (if yes, answer a-e below and provide SDS) **Hazardous Waste Identification** a. UN/Identification Number b. Proper Shipping Name EPA Hazardous Waste Code: c. DOT Hazard Class Waste Characteristics d. Packing Group e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No **REMS or REGISTRY RESTRICTIONS** (if ves. answer a-e below and provide SDS) Is there a REMS on this product? No a. UN/Identification Number If Yes, is it managed with a pharmacy registry? Website URL: b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No Med Guide Required No Is the product restricted for air shipment? If so, indicate restriction: Limited Distribution Requirement No Passenger Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: No (if yes, identify method below) Provider Name: DEA# Limited Quantity Site Enrollment Number assigned PCPDP# Consumer Commodity, ORM-D by Supplier: NPI#: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No 800-688-4697 ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: Yes **CLASS OF TRADE RESTRICTION:** URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Nο If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



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

Version 2020

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