



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

Version 2020

Introduction Type:  New Item

Final Version

Date: 8/16/2023

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):	208605		
DUNS:	858949204		
Proprietary Name (If Applicable) and Established Name:	Telmisartan Tablets USP, 20 mg.		
Selling Unit NDC:	72241-0015-22	Unit of Use NDC:	
UDI		UPC:	372241015229
		CVX Code:	
		MXV Code:	
Description:	Telmisartan Tablets USP, 20 mg		
Active Ingredient(s):	Telmisartan		
URL for Additional Product Information:	<a href="http://www.modavar.com">www.modavar.com</a>		
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:	<a href="mailto:Lewis@modavar.com">Lewis@modavar.com</a>
		Fax:	(202)355-9784
Product Therapeutic Classification:	ANTIHYPERTENSIVE		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
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>b. Contact for temperature excursion questions:</b>	
Name:	Customer Service
Number:	800-688-4697
Group E-mail:	<a href="mailto:ModavarCS@Eversana.com">ModavarCS@Eversana.com</a>
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="checkbox"/> No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="checkbox"/> Yes
<b>e. Shelf life:</b>	
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"/>
if yes, enter class # a product kit?	<input type="checkbox"/> No	Is the Product... Orphan Drug Status	<input type="checkbox"/>
if yes, list NDCs of component parts reverse numbered?	<input type="text"/>	FDA Approval Status	<input type="text"/>
co-licensed?	<input type="checkbox"/> No	Allergens Present	<input type="text" value="See Package Insert"/>
latex-free?	<input type="checkbox"/> No	Country of Origin	<input type="text" value="India"/>
preservative-free?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
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:	<input type="text" value="30"/>
		Strength:	<input type="text" value="20mg"/>
		Dosage Form:	<input type="text" value="Tablet"/>
		Product Shape:	<input type="text" value="Round"/>
		Product Color:	<input type="text" value="White to off white"/>
		Product Imprint:	<input type="text" value="debossed 'C44' on one side and plain on the"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="72241-015-01"/>
<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"/> Tube	<input type="text"/>
<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="checkbox"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> Case

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 bottle of 30ct"/>	<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="0372241000003"/>
Is product exempt from DSCSA?	<input type="checkbox"/> No	
If yes, select exemption: 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:	0.0615	2.9528	2.9528	1.5748	13.730725	1
Box/Carton/Bundle/ Inner Pack:	5.2	11.023	7.4016	4.3307	353.33244	24
Case:	11.43	16.14	12.6	10.62	2159.7257	96
Pallet:	385.49	47.2	39.37	44.09	81930.86	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		00372241015229	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	24		20372241015223	
<input checked="" type="checkbox"/> Case	96		40372241015227	
<input checked="" type="checkbox"/> Pallet	3072		50372241016221	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	\$8.35	Whsl. Code #:	<input type="text"/>
As of date:	8/16/2023	Fineline Code:	<input type="text"/>

\*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:

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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? <span style="float: right;">No</span></p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <span style="float: right;">No</span>            Is the product a CA Prop 65 reproductive toxicant? <span style="float: right;">No</span>            Does the product label bear a CA Prop 65 warning? <span style="float: right;">No</span></p> <p>c. Contact Hazard? <span style="float: right;">No</span></p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <span style="float: right;">No</span></p> <p>e. Does the product contain DEHP? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <span style="float: right;">No</span></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 &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/>            RQ Threshold: <input style="width: 50%;" type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/></p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?            (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 style="width: 50%;" type="text"/></p>	<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: 1px solid black; margin-top: 5px;"> <tr> <td><input type="checkbox"/> Organic</td> <td><input type="checkbox"/> Corrosive</td> </tr> <tr> <td><input type="checkbox"/> Inorganic</td> <td><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td><input type="checkbox"/> Steroid/Androgen</td> <td><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/></td> </tr> <tr> <td colspan="2">Is the product a NIOSH hazardous drug? <input style="width: 50%;" type="text"/></td> </tr> <tr> <td colspan="2">If yes, indicate which: <input style="width: 100%;" type="text"/></td> </tr> </table> <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">Hazardous Waste Identification</div> <table style="width: 100%; border: 1px solid black; margin-top: 5px;"> <tr> <td>EPA Hazardous Waste Code: <input style="width: 60%;" type="text"/></td> <td>Waste Characteristics <input style="width: 30%;" type="text"/></td> </tr> </table> <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? <span style="float: right;">No</span></p> <p>If Yes, is it managed with a pharmacy registry? <input style="width: 50%;" type="text"/></p> <p>Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required <span style="float: right;">No</span></p> <p>Limited Distribution Requirement <input style="width: 50%;" type="text"/></p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p><b>REMS:</b></p> <p>REMS Program Manager Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 20%;" type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input style="width: 50%;" type="text"/></p> <p>Wholesale distributor support: <input style="width: 50%;" type="text"/></p> <p>Provider Name: <input style="width: 50%;" type="text"/> DEA #: <input style="width: 20%;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 50%;" type="text"/> PCPDP#: <input style="width: 20%;" type="text"/></p> <p>NPI #: <input style="width: 20%;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> <p><b>Registry:</b></p> <p>Registry Program Contact Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 20%;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> <div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">RETURN INSTRUCTIONS</div> <p>Contact tel. # if product received damaged: <input style="width: 50%; border: 1px solid black;" type="text" value="800-688-4697"/></p> <p>Is product returnable for credit: <input style="width: 50%;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50%;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>	<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 style="width: 50%;" type="text"/>		Is the product a NIOSH hazardous drug? <input style="width: 50%;" type="text"/>		If yes, indicate which: <input style="width: 100%;" type="text"/>		EPA Hazardous Waste Code: <input style="width: 60%;" type="text"/>	Waste Characteristics <input style="width: 30%;" type="text"/>
<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														
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EPA Hazardous Waste Code: <input style="width: 60%;" type="text"/>	Waste Characteristics <input style="width: 30%;" type="text"/>														
ADD'L STORAGE INFORMATION															
<p>Is the Product...</p> <p>Controlled Substance? <span style="float: right;">No</span> Controlled Substance Code <input style="width: 50%;" type="text"/></p> <p>Controlled by State(s)? <span style="float: right;">No</span> Listed Chemical (List I or II) <input style="width: 50%;" type="text"/></p> <p>ARCOS Reportable? <span style="float: right;">No</span> If yes, indicate which: <input style="width: 50%;" type="text"/></p> <p>Schedule No. <input style="width: 50%;" type="text"/> Is it a scheduled listed chemical product?: <input style="width: 50%;" type="text"/></p>															
CLASS OF TRADE RESTRICTION:															
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50%;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 50%;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 50%;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 50%;" type="text"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p>															
MISCELLANEOUS NOTES and/or Image of Product Barcode:															
<input style="width: 100%; height: 100%;" type="text"/>															



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