



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):	208701		
DUNS:	858949204		
Proprietary Name (If Applicable) and Established Name:	Celecoxib Capsules 100mg		
Selling Unit NDC:	72241-023-10	Unit of Use NDC:	
UDI		UPC:	372241023101
		CVX Code:	
		MVX Code:	
Description:	Celecoxibe Capsules 100mg 500s		
Active Ingredient(s):	Celecoxibe 100mg		
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:	NONSTEROIDAL ANTI-INFLAMMATORY		

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"/>	Is the Product... Orphan Drug Status	<input type="text"/>
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	See Package Insert - patient specific
latex-free?	<input type="checkbox"/> No	Country of Origin	India
preservative-free?	<input type="checkbox"/> Yes	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:	500
		Strength:	100mg
		Dosage Form:	Capsule
		Product Shape:	Size "3" hard gelatin capsule
		Product Color:	fill: white to off-white powder, blue opaque cap; white opaque body
		Product Imprint:	cap imprinted "C86" and body imprinted "100"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 bottle of 500 capsules
<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="6"/> 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:	AB <input type="checkbox"/> Authorized Generic <input type="checkbox"/> If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	Celebrex®

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? <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		
Box/Case/Bundle/Inner Pack:	0.3814	3.031496	3.031496	4.685	43.055	1
Case:	2.51	9.61	6.54	6.06	380.86736	6
Pallet:	12.13	14.02	10.55	12.992	1921.6597	24
	463.728	47.24	39.37	45.28	84213.501	792

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		00372241023101	
<input checked="" type="checkbox"/> Box/Case/Bundle/Inner Pack	6		20372241023105	
<input checked="" type="checkbox"/> Case	24		40372241023109	
<input checked="" type="checkbox"/> Pallet	792		50372241023106	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$32.43	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

Version 2020

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 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? 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 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? 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 style="width: 50%;" 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 style="width: 50%;" 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 style="width: 100%;" type="text"/> </td> </tr> </table> <p style="margin-top: 5px;">Is the product a NIOSH hazardous drug? No If yes, indicate which: <input style="width: 100%;" type="text"/></p> </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 style="width: 60%;" type="text"/></td> <td style="border: none; padding: 2px;">Waste Characteristics <input style="width: 30%;" 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;">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 style="width: 100%;" type="text"/></p> <p>Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No</p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p>REMS: No</p> <p>REMS Program Manager Name: <input style="width: 60%;" type="text"/> Phone: <input style="width: 20%;" type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/></p> <p>Wholesale distributor support: <input style="width: 100%;" type="text"/></p> <p>Provider Name: <input style="width: 60%;" type="text"/> DEA #: <input style="width: 20%;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 60%;" 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>Registry: No</p> <p>Registry Program Contact Name: <input style="width: 60%;" type="text"/> Phone: <input style="width: 20%;" type="text"/></p> <p>Comments <input style="width: 100%;" 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 style="width: 100%;" type="text"/>		EPA Hazardous Waste Code: <input style="width: 60%;" type="text"/>	Waste Characteristics <input style="width: 30%;" type="text"/>
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ADD'L STORAGE INFORMATION											
<p>Is the Product...</p> <p>Controlled Substance? No Controlled Substance Code <input style="width: 100%;" 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 style="width: 100%;" type="text"/></p> <p>Schedule No. <input style="width: 100%;" 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 style="width: 100%;" type="text"/></p>											
RETURN INSTRUCTIONS											
<p>Contact tel. # if product received damaged: <input style="width: 100%;" type="text" value="800-688-4697"/></p> <p>Is product returnable for credit: Yes</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? No</p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>											
MISCELLANEOUS NOTES and/or Image of Product Barcode:											
<input style="width: 100%; height: 100%;" type="text"/>											

