

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

Version 2020						Introduction Type:	New Item	] [	x Final Version			Date:	2/24/2	1022	
PRODUCT INFORMATION								SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name:	pany Name: Modavar Pharmaceuticals LLC (U.S. Agent for Cadila Pharmaceuticals Limited) Application: AND							a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 20870:						1			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS:	858949204				1			c	ther Temperature Range I	Requirement					
Proprietary Name (If Applicable) a		me: Celecox	oxib Capsules 100mg						(write in)						
Selling Unit NDC:	72241-023-05		Unit of Use NDC:				1023057	N	lotes						
UDI			CVX Code:			MVX Code:		<u> </u>							
Description:	Celecoxibe Capsu	les 100mg 100s						ls	this product to be shipped	d to customers on ic	e?		No		
								Is	this product to be shipped	d to customers on d	ry ice?		No		
Active Ingredient(s):		Celecoxibe 100mg													
									emperature excursion qu	estions:	0				
URL for Additional Product Inform Address:		ition: www.modavar.com 1016 16th St., NW, Suite 602				Address 2:			Name:			Customer Service 800-688-4697			
City:	Washington	, INVV, Suite 6UZ			State:			Number: Group E-mail:			ModavarCS@Eversana.com				
Key Contact:	Lewis "Lew" Soars							<del> </del>	Toup E mail.		IVIOGAVAIC	JELVCISAII	a.com		
Phone Number:	(202) 868-2391				Fax:	(202)355-9784	<del>,</del>	c. Special regulations for product in any states?			No				
Product Therapeutic Classification	n:	NONSTEROIDAL A	ANTI-INFLAMMATORY					-	pecial returns requirement				No		
·					_					•					
	ADDITIO	NAL PRODUCT INF	FORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No		
The product is?			Is the Product	Direct And D	rop-Ship			P	rotect product (unit of sa	ale) from light?			No		
a legend device?		No	Is the Product	Neither		0'	100	e. Shelf life:		,			24	Months	
if yes, enter class #			Orphan Drug Status			Size:		Ir	nitial shelf life at launch (	if different):				Months	
a product kit?		No				Strength:	100mg								
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION				
component parts						Dosage Form:	Capsule				MI 1	ND0 III			
reverse numbered? co-licensed?		No No	Allermana Dracent					⊢	nit of Sale X Bottle		1 bottle of 10	NDC selling	unit?		
latex-free?		Yes	Allergens Present				Size "3" hard gelatin		Box/Carton			g. 1 Box of 10	\/iale\		
preservative-free?		Yes	See Package Insert	- patient speci	fic	Product Shape:	capsule		Ampule		(vviite-iii, e.	g. 1 DOX 01 10	viais)		
correctional institution block?		No					fill: with white to off-white		Glass		Minimum or	der quantity	?	Yes	
opioid?		No				Product Color:	powder, blue opaque cap; white		Tube				-		
Cannabinoid?		No	Country of Origin	India		Product Imprint:	cap imprinted "C86" and		Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	init dose for hospital					. roudet imprinti	body imprinted "100"		Vial Liquid Multi			_	ch package t	rpe?	
scanning?			Is this product covered un						Vial Powder Sql			Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No				Vial Power Multi Other: Write In		X	Inner/Carton	Pack		
			EOD OFNEDIO DOLLO DO	DUICTO				<u>-</u> ∐ ∟	Other: write in			Case			
			FOR GENERIC DRUG PRO	DDUCIS							1				
					Auth	orized Generic *If Au	thorized Generic, other section		PH	IARMACY ORDER	/ BILL UNIT				
I Oranga Pack Pating	fields are not applicable							Rec. sell unit to				nit to phorms	2011		
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB	Celebrex®						Nec. sen unit to	1 pill	1	x billing u	nit to pharma Each	icy:		
ii. Generio Equivalent to What Bra	iliu	COIODIONO						(Write-in, e.g. 1		_		Gram			
		DRUG SUPPLY	Y CHAIN SECURITY ACT (I	DSCSA) INFOR	RMATION			( , . 5	,			Milliliter			
												.!!			
	Does supplier meet DSCSA definition of manufacturer?  Yes  GLN: 372241000003  ITEM AND PACKING INFORMATION														
		'er'?		GL	.N:	372241000003			ITEN	I AND PACKING IN	IFORMATION	I			
Is product exempt from DSCSA?		er?	Yes No	_ GL	.N:	372241000003			ITEN	I AND PACKING IN	IFORMATION	1		# Diagon	
If yes, select exemption:		er?		_ GL _	.N:	372241000003				Dimensio	ons (US msm	its.)	Volume		
If yes, select exemption: Other exemption - Write in:		er?	No						Weight Lbs.				Volume (Cube)	# Pieces:	
If yes, select exemption: Other exemption - Write in: Is product repackaged?	avaluativa diatath.		No No		res, was origi	nal product purchased		Item/Each:		Dimensio	ons (US msm	its.)		# Pieces:	
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's		tor?	No No No	If \	res, was origi	nal product purchased			Weight Lbs.	Dimension Depth 1.8898	ons (US msm Width 1.8898	Height 3.0709	(Cube) 10.96724	1	
If yes, select exemption: Other exemption - Write in: Is product repackaged?		tor?	No No	If \	res, was origi	nal product purchased		Item/Each: Box/Carton/Bur	Weight Lbs.	Dimensio Depth	ons (US msm Width	its.) Height	(Cube)		
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's		itor?	No No No	— If y	res, was origi	nal product purchased		Box/Carton/Bur	Weight Lbs. 0.0838 dde/ 2.231	Dimension Depth 1.8898 11.811	000 (US msm Width 1.8898 8.03	3.0709 3.86	(Cube) 10.96724 366.09139	1 24	
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's		itor?	No No No	— If y	res, was origi	nal product purchased		Box/Carton/Bun Inner Pack:	Weight Lbs.	Dimension Depth 1.8898	ons (US msm Width 1.8898	Height 3.0709	(Cube) 10.96724	1	
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's		itor?	No No No	— If y	res, was origi	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	Box/Carton/Bun Inner Pack:	Weight Lbs.  0.0838  ddle/ 2.231  22.01	Dimension Depth 1.8898 11.811 17.01	000 (US msm Width 1.8898 8.03 12.6	3.0709 3.86 12.6	(Cube) 10.96724 366.09139 2700.5076	1 24 144	
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		oduct?  GTIN  Quantity  1	No No No No No No	— If y	fes, was origi ect from mfr3 yes, attach do GTIN- 00372	nal product purchased cumentation from FDA.		Box/Carton/Bur Inner Pack: Case:	Weight Lbs. 0.0838 dde/ 2.231	Dimension Depth 1.8898 11.811	000 (US msm Width 1.8898 8.03	3.0709 3.86	(Cube) 10.96724 366.09139	1 24	
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   tem/Each X   Box/Carton/Bundle/Inner Pack		GTIN Quantity  1 24	No No No No No No	— If y	fes, was origi ect from mfr2 /es, attach do GTIN- 00372 20372	nal product purchased cumentation from FDA. 14 241023057 241023051		Box/Carton/Bur Inner Pack: Case:	Weight Lbs.  0.0838  dile/ 2.231  22.01  627.102	Dimension Depth 1.8898 11.811 17.01	ns (US msm Width 1.8898 8.03 12.6 39.37	3.0709 3.86 12.6 47.244	(Cube)  10.96724  366.09139  2700.5076  87873.664	1 24 144 3888	
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 Box/Carton/Bundle/Inner Pack X Case		Quantity 1 24 144	No No No No No No	— If y	res, was originect from mfr? res, attach do  GTIN-  00372  20372  40372	nal product purchased cumentation from FDA. 14 1241023057 1241023051 1241023055		Box/Carton/Bur Inner Pack: Case:	Weight Lbs.  0.0838  ddle/ 2.231  22.01	Dimension Depth 1.8898 11.811 17.01	ns (US msm Width 1.8898 8.03 12.6 39.37	3.0709 3.86 12.6 47.244	(Cube) 10.96724 366.09139 2700.5076	1 24 144 3888	
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   tem/Each X   Box/Carton/Bundle/Inner Pack		GTIN Quantity  1 24	No No No No No No	— If y	res, was originect from mfr? res, attach do  GTIN-  00372  20372  40372	nal product purchased cumentation from FDA. 14 241023057 241023051		Box/Carton/Bur Inner Pack: Case: Pallet:	Weight Lbs.  0.0838  dile/ 2.231  22.01  627.102	Dimension Depth 1.8898 11.811 17.01	000 (US msm Width 1.8898 8.03 12.6 39.37	3.0709 3.86 12.6 47.244	(Cube)  10.96724  366.09139  2700.5076  87873.664	1 24 144 3888	
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 Box/Carton/Bundle/Inner Pack X Case		Quantity 1 24 144	No No No No No No	— If y	res, was originect from mfr? res, attach do  GTIN-  00372  20372  40372	nal product purchased cumentation from FDA. 14 1241023057 1241023051 1241023055		Box/Carton/Bur Inner Pack: Case: Pallet:	Weight Lbs.  0.0838  dde/ 2.231  22.01  627.102  COST INFORMATION	Dimension Depth 1.8898 11.811 17.01 47.244	ns (US msm Width 1.8898 8.03 12.6 39.37	Height 3.0709 3.86 12.6 47.244	(Cube)  10.96724  366.09139  2700.5076  87873.664	1 24 144 3888	
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 Box/Carton/Bundle/Inner Pack X Case		Quantity 1 24 144	No No No No No No	— If y	res, was originect from mfr? res, attach do  GTIN-  00372  20372  40372	nal product purchased cumentation from FDA. 14 1241023057 1241023051 1241023055		Box/Carton/Bur Inner Pack: Case: Pallet:	Weight Lbs.  0.0838  dde/ 2.231  22.01  627.102  COST INFORMATION	Dimension Depth 1.8898 11.811 17.01 47.244	000 (US msm Width 1.8898 8.03 12.6 39.37	Height 3.0709 3.86 12.6 47.244	(Cube)  10.96724  366.09139  2700.5076  87873.664	1 24 144 3888	
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 Box/Carton/Bundle/Inner Pack X Case		Quantity 1 24 144	No No No No No No	— If y	res, was originect from mfr? res, attach do  GTIN-  00372  20372  40372	nal product purchased cumentation from FDA. 14 1241023057 1241023051 1241023055		Box/Carton/Bur Inner Pack: Case: Pallet:	Weight Lbs.  0.0838  dde/ 2.231  22.01  627.102  COST INFORMATION	Dimension Depth 1.8898 11.811 17.01 47.244	1.8898 8.03 12.6 39.37 Vendor #:	Height 3.0709 3.86 12.6 47.244	(Cube)  10.96724  366.09139  2700.5076  87873.664	1 24 144 3888	
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 Box/Carton/Bundle/Inner Pack X Case		Quantity  1 24 144 3888	No No No NAND HIBCC PRODUCT IN	if y dir	ofes, was originect from mfrages, attach do  GTIN- 00372 20372 40372	nal product purchased cumentation from FDA. 14 1241023057 1241023051 1241023055 1241023052	Unit of Use GTIN-14	Box/Carton/Bur Inner Pack: Case: Pallet: Regular Cost Invoice Cost (W	Weight Lbs.  0.0838  Idle/ 2.231  22.01  627.102  COST INFORMATION  AC) (\$)	Dimension Depth 1.8898 11.811 17.01 47.244	1.8898 8.03 12.6 39.37 Vendor #:	Height 3.0709 3.86 12.6 47.244	(Cube)  10.96724  366.09139  2700.5076  87873.664	1 24 144 3888	
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 Box/Carton/Bundle/Inner Pack X Case	n/exemption for pr	Ouantity  1 24 144 3888	No No No NAND HIBCC PRODUCT IN	if y dir	ofes, was originect from mfrages, attach do  GTIN- 00372 20372 40372	nal product purchased of cumentation from FDA.  14 1241023057 2241023051 2241023055 2241023052 ard letter, PACKAGE INS		Box/Carton/Bur Inner Pack: Case: Pallet:  Regular Cost Invoice Cost (W As of date:	Weight Lbs.  0.0838  Idle/ 2.231  22.01  627.102  COST INFORMATION  AC) (\$)	Dimension Depth 1.8898 11.811 17.01 47.244	Nons (US msm Width 1.8898 8.03 12.6 39.37	Height 3.0709 3.86 12.6 47.244	(Cube) 10.96724 366.09139 2700.5076 87873.664	1 24 144 3888	



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