

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

Version 2021						Introduction T	уре:	New Item		Final Version			Date:	11/27/	2023
			PRODUCT INFORMATI	ON						SPECIAL HAN	DLING AND STOP	RAGE REQUI	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.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):				202437		7.11071				n – between 20 and 25 C (68° – 77° F)					
Medical Device Class, if applicable:															
DUNS:	858949204								Other Te	emperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Folic	Acid 1mg 100ct							rite in)					
Selling Unit NDC:	72241-0050-05		Unit of Use NDC:			UPC:	37224	1050053	Notes						
UDI			CVX Code:			MVX Code:									
Description:	Folic Acid 1mg 100	0ct Tablets							Is this p	oduct to be shippe	d to customers on i	ice?		No	
										oduct to be shippe				No	
Active Ingredient(s): Folic Acid															
						b. Contact for tempera	ture excursion qu	estions:							
URL for Additional Product Inform		www.modavar.com	1						Name:					er Service	
Address:	1016 16th St., NW, Suite 602				Address 2:				Number:			800-688-469			
City:	-	Washington			State:	DC	Zip: 20036		Group E-mail:			ModavarCS@Eversana.com			
Key Contact:	Tamara Solomon			Email: Fax:		lomon@modava	r.com	c. Special regulations for product in any states?			No				
Phone Number:	202-355-9785 x 4				Fax: 202-355-9784										
Product Therapeutic Classificatio	on:								Special	returns requiremen	ts for this product?			No	
		ONAL PRODUCT IN				PRODUCT	DESCRIPTION	FORMATION		of colo) unvieto?				Vee	
	ADDITIC	DNAL PRODUCT IN		<b>D</b> 1 + 4 + 10		FRODUCT	DESCRIPTION INFORMATION d. Store product (unit of sale) upright?					Yes			
The product is?			Is the Product	Direct And D	rop-Ship		100			product (unit of sa	ale) from light?			Yes	
a legend device?		No	Is the Product	Neither		Size:	100ct		e. Shelf life:	olf life at launch	if different's			24	Months Months
if yes, enter class # a product kit?			Orphan Drug Status				1MG		Initial S	nelf life at launch (	if different):				Months
if yes, list NDCs of			FDA Approval Status			Strength:	TWO					MATION			
component parts			T DA Approval otatus				Tablets								
reverse numbered?		No				Dosage Form	n:		Unit of S	Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x	Bottle		1 bottle of 10	00ct tablets		
latex-free?		Yes	See Packa	ao Incort		Product Sha	Round, b	oi convex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Jee r acka	gemsen		Froduct Sha	pe.			Ampule				_	
correctional institution block?		No				Product Cold	Yellow			Glass		Minimum o	rder quantity	?	Yes
opioid?		No				i iouuor oon				Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp		d ,debossed with		Vial Liquid Sgl					_
If Unit Dose, is item bar coded to u hospital scanning?	unit dose for									Vial Liquid Multi Vial Powder Sol			many of wh Each	ich package t	ype?
If Unit Dose, indicate NDC here:			Is this product covered un Trade Agreements Act (TA		No					Vial Powder Sqi Vial Power Multi		24	Inner/Cartor	Pack	
in oniti bose, indicate NDC fiele.					NO					Other: Write In			Case	// dok	
			FOR GENERIC DRUG PRO	DUCTS									1		
					Au	thorized Generic	*If Authorized G	eneric, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AA						section fields ar	e not applicable	Rec. sell unit to custor	mer?		Rx billing u	nit to nharm	acv:	
II. Generic Equivalent to What Bra					Folvite®			1 pill			x Each				
•								(Write-in, e.g. 1 Vial)			Gram				
		DRUG SUPPL	Y CHAIN SECURITY ACT (D	SCSA) INFOF	RMATION								Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes	_	GLN:		372241000003			ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.	Dimensi	ions (US msn	nts.)		Saleable #
Other exemption - Write in:										Weight Ebs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			Na			riginal product			Item/Each:	0.5	1.53	1.536	2.75	6.46272	1
Is product sold by manufacturer's			No	-		rect from mfr?			Bay/Cartan/Bun II-/						
Has FDA granted waiver/exceptio If yes, attach documentation from		oduct?	INO		Provide sour	ce manufacturer fo	or repackaged p	roduct	Box/Carton/Bundle/ Inner Pack:	2.64	7.4	4.33	11.02	353.10284	24
in yes, attach documentation no	III FDA.								Case:						
		GTI	N AND HIBCC PRODUCT INF	ORMATION					ouse.	10.56	13.4	10.63	17.32	2467.0954	96
									Pallet:		17.01				
Saleable Unit of Measure	Sa	aleable Quantity	HIBCC		GTI	N-14	Unit of	Use GTIN-14		357.72	47.24	39.37	47.24	87858.785	3072
x Item/Each		1				0372241050053									
X Box/Carton/Bundle/Inner Pack		24				20372241050057			COS	WHOLESALER USE ONLY:					
X Case		96				0372241050051	_					_			
X Pallet 3072			50372241050058			Regular Cost			Vendor #:						
	-						-		Invoice Cost (WAC) (\$)		\$4.80	Whsl. Code			
	-				-		-		As of date:	11/27/2023		Fineline Co	ae:		
	-						-		AS OF UALE:	. 1/21/2020					
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.															
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:															
suse provide any additional init						500 now p. 5 101	2 soignated DIU	P Sink Sink.	Sigilatu			Juna			

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

Version 2021 For Designat	ed Drop Ship Only Products, Please Use Page 3				
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a Folic Acid 1mg 100ct Does the product label bear a CA Prop 65 warning? No	Organic	Corrosive Oxidizer Contact Hazard			
c. Contact Hazard?     No     d. Does this product require special clean-up instructions?     (If yes, attach SDS with special instructions.)     e. Does the product contain DEHP?     No     Is this product regulated for shipment by DOT?     (if yes, answer a-e below and provide SDS)     a. UN/Identii	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:	No No			
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	Haza EPA Hazardous Waste Code:	rdous Waste Identification Waste Characteristics			
(if yes, answer a-e below and provide SDS) a. UN/dentification Number	REMS or REGISTRY RESTRICTIONS				
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	Is there a REMS on this product? Website URL:	No			
e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: No	Med Guide Required	No			
Passenger See Package Insert Cargo Passenger & Cargo	Comments / Details: (For example, iPledge program?)				
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit, DOT-SP	Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: Comments	No       DEA #:       NCPDP#:       NPI #:			
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry:				
E INFORMATION Is the Product	Comments	Phone:			
Controlled Substance?         No         Controlled Substance Code           Controlled by State(s)?         No         Listed Chemical (List I or II)           ARCOS Reportable?         No         If yes, indicate which:	RETURN INSTRUCTIONS Contact tel. # if product received damaged:	800-688-4697			
Schedule No. Is it a scheduled listed chemical product?:	Is product returnable for credit:	Yes			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices     No	URL/Link to returns policy: ModavarCS@Eve	ersana.com			
Restricted to retail pharmacy only:         No           Restricted to hospital, clinics, and physician offices only:         No           Restricted from US territories? (explain in comments)         No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?				
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

Version 2021	FOR DESIGNATED DROP SHIP PRODUCT ONLY -	f not a designated drop ship, do not complete.	
Order Method f	or Designated Drop Ship Product	Standard Order Receipt and Processing	
Purchase orders may be accepted by: a. EDI b. Autofax	Fax Number:	Purchase order daily receipt cut off time by supplier	
c. Fax d. Phone only	Fax Number:	Shipping lead time of PO: Hours	Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / c Folic Acid 1mg	Site Address:       Name:       Phone:	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:	
Expedited Freight Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing	
Expedited freight fees billed with each order Drop Ship service fee billed with each order Drop Ship miscellaneous fees billed: Comments:			Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:	
Clas	ss of Trade Restriction:	PO Receipt Cut off time:	
No restriction: Select YES if sold to retail ph Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician Restricted from US territories? (explain in co Comments:		Saturday Overnight receipt available:         PO Receipt Cut off time:         Order receipt method:         Phone:         Fax:         EDI:         Overnight Fees apply:         Other fees apply:	
Other Data Info	ormation 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?	5?
eous Notes:		Folvite®	
	ADDITION	INFOF Is product order for scheduled patient procedure? Is product order for restocking purposes?	